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RECEPTIVE MUSIC THERAPY IN ONCOLOGY: GUIDED IMAGERY AND MUSIC DURING THE COURSE OF ACTIVE TREATMENT FOR BREAST AND GYNECOLOGIC CANCER

A TWO-PART PRELIMINARY INVESTIGATION

BY
EVANGELIA PAPANIKOLAOU

DISSERTATION SUBMITTED 2020



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CV

Evangelia Papanikolaou is a music therapist and a GIM therapist, trainer, and supervisor. She has been involved in the development of the music therapy profession and practice in Greece for over 20 years and is currently the scientific director of “SONORA-Organization for Music Therapy & Research” in Athens. She completed her music studies in Greece. Later, she studied for a master's degree (MA) in Music Therapy at Roehampton University (UK), and for a post-graduate diploma in Clinical Neurosciences & Immunology. She finished her studies in Guided Imagery and Music (GIM) in 2008 and became a GIM trainer in 2012. She has also received complementary training in psychodynamic and systemic psychotherapies and has attended shorter trainings in specialist music therapy methods, such as music therapy in the Neonatal Intensive Care Units, pain management, as well as using vocal techniques in therapy.

Evangelia has worked extensively in both London and Athens in many different clinical areas, including mental health/psychological trauma, psychiatry (acute and rehabilitation), eating disorders (adolescents), developmental disorders, people with speech problems, and perinatal care. Over the last decade, her main focus has been in oncology, working with individuals and groups in the curative or rehabilitative phase, with an emphasis on using receptive music therapy and Music Imagery (MI) approaches as well as the GIM method. Oncology forms the main focus in her research project for the PhD scholarship that she was granted at Aalborg University, Denmark, in November 2015.

She is an adjunct professor at Hellenic American University (Athens), an external lecturer at the University of Athens School of Medicine, and a supervisor for Artez Conservatory, MA in Music Therapy (the Netherlands). She has been lecturing widely in music therapy whilst in her role as GIM trainer, she has run introductory seminars or GIM and MI trainings in Greece, Cyprus, UK, Israel, the Netherlands, Portugal, Turkey, UAE, Brazil, etc. She has also provided supervision for both music therapy students and GIM trainees.

Evangelia is currently an advisory board member for the journal *Dialogues in Clinical Neuroscience & Mental Health*. She was a former advisory board member and guest editor for the Music Therapy e-journal *Approaches*. She has served as a member and head of scientific and organizational committees of various international music therapy conferences. She was the founding President of the Hellenic Association of Professional Music Therapists (ESPEM), and Country Representative at the European Music Therapy Confederation (EMTC) for the period 2014-2020. She is a member of the Educational Committee of the European Association for Music & Imagery.

ENGLISH SUMMARY

This project is a very first attempt to explore and evaluate the potential of the receptive music therapy method Guided Imagery and Music (GIM) as a brief psychological intervention for women who are receiving chemotherapy or radiotherapy in an outpatient Greek Gynecologic Oncology hospital unit. A GIM session involves an initial conversation followed by listening to a specifically designed sequence of music pieces in a relaxed state. The client describes to the therapist any images, emotions, sensations, or thoughts elicited and supported by the music, and afterwards, there is a verbal processing of the experience.

The overall preliminary investigation has two main aims: the first aim is to examine the feasibility of such a complementary intervention in a hospital setting that has no intervention other than standard medical care. Since there is no systematic evidence concerning applications of GIM during the course of active medical treatment for cancer, the second aim of this preliminary investigation is to pilot a randomized controlled research design inquiring into the role of GIM as a supportive therapy for women during the course of chemotherapy or radiotherapy and its potential effect on relevant psychological variables. Should findings indicate that GIM can be an effective treatment, this preliminary knowledge can inform clinical practice and give suggestions for a large- scale research protocol.

Therefore, this thesis consists of two investigations. The first investigation is a mixed-methods feasibility study including a qualitative and quantitative part, with a small purposive sample of four participants. Women received a series of six approximately weekly, individual, short GIM sessions, and they completed the FACT-G and HADS questionnaires at two time points (baseline/pre and post therapy) and 10-point Likert scales for fatigue and hope, before and after each single session. This was followed by a qualitative interview with focus on the perceived experience and participants' feedback on feasibility and delivery of the intervention (frequency, location, length, etc.). *Results:* Positive changes in mood, fatigue levels, and hope were reported by the participants while the changes in hope and fatigue were also supported by the results of the Likert scales, but, no significant changes to self-reported anxiety and depression and QoL as measured by HADS and FACT-G were

found. Consequently, the variables of fatigue, hope, and mood have formulated the research questions for the second part of the investigation.

The second investigation is an experimental, randomized controlled trial (RCT) pilot study, in which the questions, procedure, and design were adjusted and constructed according to the feasibility's outcomes and indicated direction. Participants ($N = 20$) with breast and gynecologic cancer were randomized into a Treatment group and a Control group. The Treatment group ($n = 10$) received six approximately weekly, individual, short GIM sessions in addition to standard care, and the Control group ($n = 10$) received standard medical care and two supportive verbal psychotherapy sessions, one at baseline and another after 6 weeks. Participants in both groups completed the same questionnaires on mood, fatigue, and hope. Profile of Mood States (Brief), Cancer Fatigue Scale (CFS) and Herth Hope Index (HHI) were used at baseline and post-treatment, and visual analogues scales (VAS) for Hope and Fatigue were used for 6 consecutive weeks. *Results:* VAS for Hope and Fatigue showed significant changes in increasing hope and decreasing fatigue in the Intervention group, but there were no significant pre-post within-group differences for the three standardized questionnaires HHI, CFS, and POMS; however, the Intervention group showed medium pre-post effect sizes on all three measures. GIM showed promise to be effective in decreasing fatigue, increasing hope, and mitigating distressed mood for women undergoing medical treatment for breast or gynecologic cancer.

The ultimate aim was not only to obtain preliminary documentation on the potential effect of the intervention but also to gain data on the practicality of GIM as a psychological therapy during the course of active treatment for breast or gynecologic cancer. Within this context, one other purpose of this investigation was to gather preliminary information as to whether a full trial could be feasible to conduct in the Greek hospital system. For this purpose, information was gathered about various components that are necessary for a trial such as recruitment, adherence, and variability outcomes, and explored whether they can work properly together. According to these, recruitment must be assisted by medical staff, and persistence by the researcher is needed to keep up with allocation and total completion time. Cultural and socioeconomic issues should be considered as they may play a major role in patients' compliance and engagement with therapy. Treatment fidelity issues need to be also taken into account; although GIM in shorter form and simplified music is feasible in such population, session format and therapeutic processes must

be handled with flexibility to accommodate the needs of a clinical population with limited resources.

Overall, this PhD study contributes to clinical practice and research by providing new evidence on the role and significance of GIM in a new and under-researched clinical area, specifically, during a course of active cancer treatment. The promising quantitative results in combination with the qualitative findings, provide a multi-dimensional understanding of the effects of GIM for the study participants as well as of its role and feasibility in such a clinical setting. The importance of enhancing hope, and positively addressing fatigue and mood for women cancer patients becomes evident from these preliminary results. However, in this small-scale investigation with sample from only one hospital unit, the results cannot be generalized. Another limitation of this study is the inclusion of participants with first cancer diagnosis as well as advanced cancer patients, two categories that often have a different psychological profile due to stage of disease, suggesting the need for a more homogenous sample in the future. There are discrepancies in the findings between repeated measures VAS results showing statistical significance and the psychometric instruments HHI, CFS, and POMS that did not show significance. The reason for this is unclear, and further research is needed to clarify this. Therefore, future research is recommended not only on qualitative, in-depth experiences of the patients, but also on measurable psychological outcomes in a larger-scale study.

It should be clarified that the term *Gynecologic Oncology* is used as an umbrella term for breast cancer (BC) as well as all types of gynecologic cancers (GC), since the hospital unit that hosted this study provides care for women with the aforementioned cancer types. However, little evidence in general has been found in the literature regarding patients with GC care and their psychological needs, and there is no evidence about any specific characteristics of patients with gynecologic cancers in Greece. Thus, the emphasis of the first part (feasibility study) was on patients with GC only, in order to identify any specific needs or characteristics that could have been pointed out by the participants of this Greek sample. However, since no particular trends were revealed or suggested by the participants, women with breast cancer also were included in the sample of the RCT pilot to enlarge sample size of the research investigation.

DANSK RESUME

Dette studie er et første forsøg på at undersøge og evaluere potentialet af den receptive musikterapi metode Guided Imagery and Music (GIM) som psykologisk korttidsintervention for kvinder, der modtager kemoterapi eller stråleterapi i ambulant behandling for bryst- eller gynækologisk cancer på et græsk hospital. En GIM-behandling indeholder en indledende samtale, der efterfølges af musiklytning til en specialdesignet sekvens af klassiske satser. Under lytningen bringes klienten i en afspændt tilstand. Klienten beskriver undervejs de billeder, følelser, sansninger og/eller tanker, der opstår under musiklytningen, og som understøttes af musikken. Den sidste del af sessionen forgår som en samtale om oplevelsen.

Den samlede foreløbige undersøgelse har to overordnede formål: Det første er at bestemme gennemførligheden af en sådan komplementær intervention i en hospitals-setting, hvor der ellers kun tilbydes medicinsk standardbehandling, da der i litteraturen ikke findes systematiske undersøgelser af eller evidens for anvendelse af GIM i forbindelse med aktiv medicinsk behandling af cancer. Det andet mål med studiet er at vurdere egnetheden af et randomiseret kontrolleret forskningsdesign af den effekt, som GIM-behandling kan have på udvalgte psykologiske variable, når den anvendes som støttende terapi for kvinder i løbet af deres kemo- og strålebehandling. Hvis resultaterne af forundersøgelsen indikerer, at GIM kan være en effektiv behandling, vil denne foreløbige viden kunne informere klinisk praksis og generere hypoteser for videre forskning i større skala.

Denne afhandling består således af to undersøgelser: Den første undersøgelse er et gennemførlighedsstudie med et to-trins mixed method-design, hvor et sample bestående af fire deltagere først underkastedes en kvantitativ, herefter en kvalitativ undersøgelse: Kvinderne i undersøgelsesgruppen modtog en serie af seks omtrent ugentlige individuelle korte GIM-sessioner. I forbindelse hermed udfyldte de før og efter hver session (baseline/præ- og postterapi) FACT-G- og HADS-spørgeskemaer og 10-punkts Likert-skalaer for træthed og håb. Disse undersøgelser efterfulgtes af et kvalitativt interview med fokus på deltagernes oplevelse af behandlingen og feedback på måden, hvorpå den blev gennemført, fx i forhold til hyppighed, lokalitet og varighed. *Resultater:* Deltagerne rapporterede om positive forandringer i forhold til humør/stemning, træthedsniveau og håb, fund, der

blev bakket op af data fra Likert-skala-målingerne, mens der ikke blev fundet signifikante ændringer af det selvrapporterede niveau af angst, depression og QoL som målt ud fra HADS- og FACT-G-spørgeskemaerne. På den baggrund er der i anden del af undersøgelsen rejst forskningsspørgsmål om træthed, håb og humør.

Den anden undersøgelse udgøres af en RCT-undersøgelse, et eksperimentelt randomiseret kontrolleret studie, hvor spørgsmål, procedure og design blev evalueret og justeret ud fra fund i det første studie. Her blev 20 kvinder (n=20) ud fra lodtrækning inddelt i en interventionsgruppe (en behandlingsgruppe) og en kontrolgruppe. Interventionsgruppen (n=10) modtog ud over den medicinske standardbehandling seks omtrent ugentlige individuelle korte GIM-sessioner, mens kontrolgruppen ud over medicinsk standardbehandling modtog to støttende verbale psykoterapisessioner: den første ved baseline, den anden efter seks uger. Både deltagere fra interventions- og kontrolgruppe besvarede spørgeskemaer om humør, træthed og håb ved baseline, dvs. præterapi, og efter undersøgelsen, dvs. postterapi, hhv. Profile of Mood States (POMS-brief), Cancer Fatigue Scale (CFS) og Herth Hope Index (HHI). Derudover måltes værdier for håb og træthed med anvendelse af Visuelle Analoge Skalaer (VAS) i alle seks uger. *Resultater:* VAS for håb og træthed viste signifikante forandringer i forhold til øget håb og mindsket træthed i interventionsgruppen. Der sås ingen signifikante forskelle mellem grupperne ud fra deres besvarelser af de tre standardiserede spørgeskemaer HHI, CFS og POMS. Der blev imidlertid præ- og posttest fundet medium effect sizes for interventionsgruppen på alle tre effektmål. Ud fra disse fund tyder det på, at GIM-behandling kan reducere træthed, øge håbet samt løfte humør og stemningsleje hos kvinder, der i øvrigt er i medicinsk standardbehandling for bryst- eller gynækologisk kræft.

Det samlede mål med undersøgelsen var ikke kun at skaffe foreløbig dokumentation for effekten af GIM som intervention, men også at indsamle data af mere praktisk karakter om GIM som psykoterapeutisk intervention under aktiv medicinsk standardbehandling af bryst- og gynækologisk cancer. I denne sammenhæng var et andet formål tillige at indsamle foreløbige data til en vurdering af, om det er realistisk at gennemføre en undersøgelse af GIM som metode i en større skala inden for det græske hospitalssystem. Til dette formål blev også indsamlet data, som vil kunne indgå i en sådan undersøgelse, bl.a. om rekruttering, deltagernes evne til at holde fast i aftalt behandling (adherence) og andre variable. Ifølge disse indsamlede

informationer skal rekruttering foretages i samarbejde med det medicinske personale, og forskerens vedholdenhed er behøvet i forhold til allokering af deltagerne og den samlede gennemførelsestid. Kulturelle og socioøkonomiske forhold bør også tages i betragtning, da de kan spille en vigtig rolle for deltagernes evne til at overholde behandlingsrammen og til at engagere sig i terapien. Der skal også tages hensyn til problemstillinger knyttet til behandlingsvaliditet (treatment fidelity). For selvom GIM i kort form og med tilpasset musik har vist sig velegnet til den undersøgte målgruppe, skal dens sessionsformat og håndtering af terapeutiske processer også kunne tilpasses en klinisk population med begrænsede ressourcer.

Samlet set bidrager nærværende ph.d.-undersøgelse til klinisk praksis og forskning med sin dokumentation af og evidens om den rolle og betydning, som GIM kan have inden for et nyt og underudforsket klinisk område, specifikt som supplerende behandlingsmetode under aktiv medicinsk cancerbehandling af bryst- og gynækologisk cancer. De lovende kvantitative resultater giver sammen med de kvalitative fund en multidimensionel forståelse af den effekt, som GIM kan have på deltagerne, men også på GIM's rolle og gennemførlighed inden for den undersøgte kliniske setting. Undersøgelsens resultater peger foreløbigt på vigtigheden af at styrke håbet og tackle træthed og humør hos kræftsyge kvinder. Resultaterne kan dog ikke generaliseres: Der er kun rekrutteret deltagere fra ét hospital, og datagrundlaget er lille. En anden begrænsning i studiet er, at det både inkluderer deltagere, der er ramt af cancer for første gang såvel som deltagere, der er kendte med cancer. Disse to grupper af cancerpatienter har ofte forskellige psykologiske profiler som følge af at være i forskellige faser af sygdommen, hvilket peger på nødvendigheden af i fremtidige studier at undersøge udsnit af grupper, der er mere homogene. Der er desuden uoverensstemmelser mellem de gentagne VAS-målinger, der viste statistisk signifikans, og de psykometriske instrumenter HHO, CFS og POMS, der ikke viste signifikans. Grunden til uoverensstemmelsen er foreløbigt ukendt, og der er brug for mere forskning for at afklare årsagen til denne. På den baggrund anbefales det, at fremtidig forskning udføres i stor skala og såvel inddrager kvalitative undersøgelser af deltageroplevelser som målbare psykologiske variable.

Det skal afsluttende præciseres, hvorfor begrebet 'gynækologisk onkologi' i afhandlingen benyttes som paraplybegreb for både brystcancer (BC) og alle typer af gynækologisk cancer (GC): Det inkluderer de cancertyper, som den

hospitalsafdeling, der var vært for nærværende studie, tilbød behandling for. Litteratursøgningen har vist, at der generelt er sparsom evidens for specifikke psykologiske behov hos brystcancerpatienter. Der kan heller ikke findes evidens for specifikke karakteristika for græske patienter med forskellige typer af gynækologisk cancer. Derfor er fokus i den første del af studiet om gennemførlighed netop på patienter med gynækologisk cancer med det formål at identificere evt. specifikke behov eller karakteristika for denne målgruppe i en græsk population. Da undersøgelsen ikke pegede på sådanne tendenser, blev kvinder med brystcancer også inkluderet i kohorten i den anden del af studiet, RCT-undersøgelsen, med det formål at forøge antallet af deltagere.

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actively helped with recruitment at all stages by personally contacting the patients and encouraging their participation, and of her assistant Marina Giannouri, psychologist, for coordinating the process and liaising directly with me. My deepest appreciation goes to both these women, for supporting and bearing with me until the completion of the study.

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Thank you, all dear friends, colleagues, and students of mine, for the support and faith throughout. Thank you, my dear mum and dad, for everything you offered me to become the person I am.

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LIST OF PHD PUBLICATIONS

Article 1:

Papanikolaou, E. (2020). Guided Imagery and Music (GIM) during active treatment for cancer: Considerations for clinical practice. *Journal of the Association for Music & Imagery*, 17, 55-71.

Article 2:

Papanikolaou, E., McKinney, C., & Hannibal, N. (2020). Guided Imagery and Music during the course of active treatment for gynecologic cancer: Results of a feasibility study. *Music and Medicine*, 12, 199-209.

Article 3:

Papanikolaou, E., McKinney, C., Hannibal, N., Tsouvelas, G., Panoskaltsis, T., & Karageorgopoulou, S. (2020). The Guided Imagery and Music method during the course of active treatment for breast and gynecologic cancer: An RCT pilot. (submitted for publication).[/]

[/] The second part of this PhD investigation (RCT pilot study) is registered as a clinical trial at clinicaltrials.gov with trial registration identifier number: NCT03936075

CHAPTER 1. INTRODUCTION

In this introduction chapter, I will explain the layout of the overall project and how this thesis is structured. I will explain my motivation for this investigation and describe the background that led my inspiration and decision to conduct this research project. I also will elaborate on the importance of the variables that inform the research questions of the investigation, based on the literature on up-to-date research in oncology, especially on gynecologic and breast cancer patients and their care. In addition, I will highlight the role and importance of psychological therapies within an integrative model, with an emphasis on creative arts therapies and the Guided Imagery and Music method.

1.1. OVERALL STRUCTURE OF THE STUDY AND LINKING TEXT

This is an article-based PhD thesis according to the standards of Aalborg University, and is a project consisting of two separate studies (a feasibility study and a randomized controlled trial pilot) described in three articles (summarized in the thesis), and accompanied by the present linking text that guides the reader through the different steps of the process, and which is divided into four chapters. The linking text aims to bind together the three publications into a single narrative, and also to include further information that was excluded from the articles, thereby enriching the reader with additional aspects that did not fit into the articles' structure or content.

Chapter 1 is the introduction to the project. It provides all background information; description of the population in question; specific needs of the population; description of the intervention (GIM); the protocol to be followed within a specific integrative perspective; facts on the use of GIM in cancer, as shown from the current literature; and rationale of the investigation.

Chapter 2 provides information about the methodology, more notably, describes the purpose of the study, the rationale of the methodological design, the paradigm, the pre-understanding, and the personal stance of the main researcher. This is followed by **Article 1** (summarized in the linking text), which highlights the theory and qualitative aspects that frame the study. It describes the theoretical framework, the role of imagery, the role of music and considerations for music selections, as well as considerations and factors that

confine clinical practice and the therapeutic processes. The article concludes with a short clinical vignette based on the personal experience of one of the participants. **Article 1** is linked with a summary of **Article 2** which presents the layout of the feasibility design and then summarizes and discusses the results of the feasibility study.

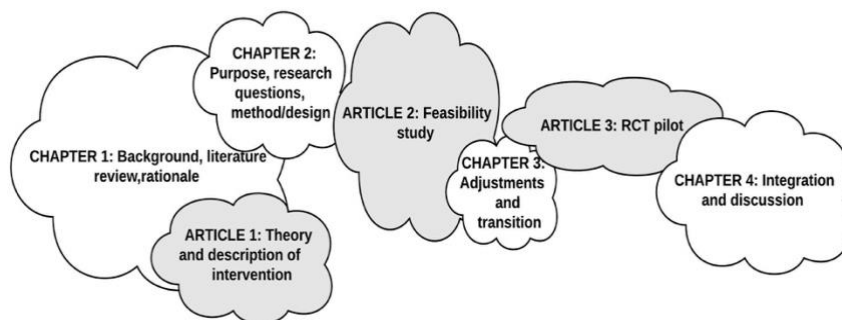


Figure 1-1. Outline of the thesis structure

Chapter 3 is a transition between the feasibility and the second study, the experimental randomized controlled trial (RCT) pilot. It links the results of the feasibility study and the “highlights” that lead to essential changes in the design or methodology towards the RCT pilot. This is followed by a summary of **Article 3** which describes the pilot and presents its results.

Chapter 4 is an integration of the results of the two parts of this study and its main aspects, including discussion of important findings and learnings, and the new perspectives this preliminary investigation adds to clinical and research knowledge and understanding. The chapter also includes a discussion on the limitations, considerations or suggestions for future research, and a general conclusion as an epilogue.

1.2. MOTIVATION

As a person, music therapist, clinician, and recently researcher, I have always had the curiosity to find out more how our mind interacts with the body. I was

intrigued by the fascinating mechanisms behind the complex processes and the potential role of music as influential on the way our mind perceives and “metabolizes” music on a physical or psychological level, and how clinicians and scientists can gain therapeutic benefits, if they make appropriate use of it. This has been one of my initial motivations to become a music therapist and my choice to discover more about the role of music in the use against disease, especially cancer.

My motivation for this project started soon after a big campaign for women with cancer, launched in my home country, Greece, by a well-known pharmaceutical company. The campaign was particularly promoting “Integrative Oncology,” as a new “perspective” on cancer treatment, introducing a series of seminars and experiential workshops on various complementary and alternative medicine (CAM) disciplines. I took part under the umbrella of “Creative Psychological Interventions” section, offering music therapy, Guided Imagery and Music (GIM) and Music Imagery (MI) workshops, and to my surprise, they had the biggest participation and better feedback compared to all other therapies offered. On top of that, the GIM workshops turned out to be slightly more popular compared to the interactive music therapy workshops.

During the following period, I began to investigate possibilities to explore more on CAM in cancer care in Greece, and especially the potential development of GIM within this field. I had come to realize that there are not many supportive psychological interventions offered in my country for these women. In a country where cancer is a taboo word, there is a great need for cancer patients to find a safe place, absorb new experiences and discover new paths in dealing with the disease and its implications in their everyday life. I also came to realize that services and attention is mostly focused on women with breast cancer—a type of cancer that has been studied quite extensively and was the subject of the majority of the trials conducted on psychological interventions (Antoni, 2013)—whereas, there is little emphasis on women with gynecologic cancer (GC), although GC is quite prominent and appears with increased needs, as explained below.

1.3. BACKGROUND TO THE STUDY

Despite the ongoing advancements in cancer care, receiving a cancer diagnosis is usually followed by a major life crisis related to issues of life, death and survival. The person is at risk of experiencing extensive physical, emotional, and social suffering as well as uncertainty about their treatment options, as they deal with the challenges of receiving the diagnosis and the treatment (Boehm et al., 2014; Shelby et al., 2002).

Regardless of these challenges, there is considerable evidence that cancer patients frequently show an increased level of unaddressed psychosocial needs, which contributes to the stress related to having the illness and to poorer life quality (Fitzpatrick, 2018; Sutherland, Hill, Morand, Pruden & McLachlan, 2009). Women with cancer exhibit higher levels of distress compared to men (Herschbach et al., 2008). Especially for females with GC, not only are the incidence and mortality rates high, but even if the women survive treatment, the data suggest that they are at greater risk for psychological maladjustment than other cancer survivors. In a study by Johnson, Gold, and Wyche (2010), it is reported that over half of women with GC reported high distress levels, especially younger or single women. Gómez-Campelo, Bragado-Álvarez, Hernández-Lloreda (2014) also point out the significantly greater psychological distress rates for younger women who undergo surgery, as opposed to the older ones. Besides, there is supportive evidence towards the increased psychosocial needs of cancer patients and especially females with GC when they are still in treatment (Steele & Fitch, 2008) and their unmet needs for support (Faller et al., 2017). These facts are comprehensive, especially when appreciating how detrimental the effects are to a woman's sense of female identity. The patient may not feel like a "whole," her interpersonal relationships feel threatened, she may no longer feel attractive, or she may lose the capacity of motherhood (Gotheridge & Dresner, 2002; Sacerdoti, Luciana & Koopman, 2011). Because of these reported amplified needs, this study focuses on women undergoing adjuvant treatment for cancer via chemotherapy, radiotherapy, or hormone-suppression drugs.

1.3.1. CANCER WITHIN A GREEK CONTEXT

According to Economou, Kaitelidou, Karanikolos, and Maresso (2017), cancer is the second larger cause of death in Greece after cardiovascular diseases, and according to the World Health Organization's "GLOBOCAN" project

(International Agency for Research in Cancer, 2018), breast cancer is the first and gynecologic cancer (corpus uteri) is the third most frequent cancer for females in Greece. In a Greek study, authors report that a significant proportion of Greek cancer patients experience compromises in their quality of life (QoL). Mainly, they report intense anxiety and depression during their first chemotherapy treatment, as well as severe emotional distress during the beginning and the ending of treatment (Iconomou, Mega, Koutras, Iconomou & Kalofonos, 2004).

Cancer patients in Greece experience dramatic consequences in their lives because of cancer. Professionally, they undergo decommissioning or stagnation in their career development under the guise of not being over-stressed. In their personal and family lives, they often face pity and rejection, creating an extra burden for the patients, who may feel guilty about their situation. Additionally, extra burden and existential anxiety is created by the fact that, because of the cultural mentality, the word “cancer” is treated as a taboo word by the Greek society, causing social stigmatization and devaluation of the personality and human dignity. In addition to that, in their most difficult time, patients need to confront phenomena and characteristics of the hospital and overall Health System that emotionally depletes them, physically strain or even discourage them. They feel weak to face the often thorny, complicated structures and bureaucratic obstacles of the Health System and/or the high cost of the disease, especially after the cuts to the health budget and funds as a result of the economic crisis. At this most critical moment of their lives, the patients are confronted with all these contemporary health, social, cultural, and moral deficits of the society, which reinforce their guilt and make the fight against the disease almost unbearable. These burdens often cannot be sufficiently “contained” neither by the family and society nor by the medical staff (General Secretary of Public Health, 2015).

Although the need for psychological support is obvious, there is usually no provision for any form of complementary/psychological therapies in the Greek hospitals. Most settings provide only standard medical care, and the treatment approach is mainly based on the biological understanding of the disease. Psychosocial and other complementary therapies are not formally introduced, and the knowledge of the majority of the physicians and their acceptance are low (Theodoropoulos, Manolopoulos, Georgi, Bohlmann & Münstedt, 2005).

However, medical doctors who collaborated in this study supported this innovative idea with curiosity and interest. The project took place in the Outpatient Gynecologic Oncology Unit of a Greek Hospital in collaboration with the head physician and his team of medical oncologists and surgeons. Under the circumstances, introducing a complementary therapy within such a context is one of the challenges of this project; it may be seen as an educational aspect for physicians and service providers regarding the efficacy of psychological therapies for specific aspects of gynecologic oncology patients' general emotional, social, and physical state.

1.4. QUALITY OF LIFE AND PSYCHOLOGICAL DISTURBANCES

In this project and in general assessing a person's subjective experience of their life quality is very important when a person is dealing with illness. QoL is a concept that provides information about the functioning of cancer patients. Measuring QoL serves as an indicator of how they experience or evaluate their own lives, and a valuable addition to clinical data. Assessing QoL means taking into account the experience of the patient with gynecologic cancer with regards to her wellbeing and various aspects of it, including social, emotional, physical, spiritual, and functional aspects within a specific cultural and personal values system (Ferrell, Smith, Cullinane & Melancon, 2003; Jensen & Cella, 2014; WHO-Study Protocol, 1993). As described in the previous section, Greek cancer patients are at high risk of compromised quality of life and augmented emotional and social needs as a result of the socio-cultural and economic situation of the country and the cultural mentality. Psychological, supportive therapy could be provided as a treatment to address various aspects of these women's health and well-being, such as general quality of life (QoL) and individual domains of QoL such as mood, fatigue, and hope.

QoL is strongly affected in patients in gynecologic oncology, and this raises the importance of including overall QoL measurements, especially in the phase of active treatment (Holt et al., 2015). Thus, overall QoL for persons in cancer treatment is one of the aspects I will examine in this research because of its importance for cancer and women sufferers from gynecologic cancers and the implications for psychological disturbances, as I will explain in this section.

The treatment of cancer has three goals: improvement of the cure rate, extension of survival time, and improvement of QoL (Penson, Wenzel, Vergote & Cella, 2006). The gains in patient survival time from the advances in detection and standard chemotherapy or radiotherapy treatment for gynecologic malignancies are often associated with a variety of toxicities that diminish QoL standards (Wenzel et al., 2003). QoL levels are lower in patients with GC as opposed to breast cancer (Faller et al, 2017). Women with GC often face specific challenges related to the type of tumor and its treatment, and the symptoms remain in GC survivors even after completion of treatment (Rowland, Ruskin, Greenwade, Moore, & Matzo, 2016; Wärja, 2018). However, the majority of the factors that compromise QoL are amenable to supportive care interventions and can be evaluated at the time of primary treatment (Osann et al., 2014).

GC may entail additional psychological consequences as the body parts involved are emotionally charged due to their association with femininity, sexuality, and motherhood (Capone, Good, Westie & Jacobson, 1980). The emotional challenges that can impair QoL include anxiety, depression, guilt, anger, and concerns about changes in life patterns, capacity to cope, spirituality, body image, fear of pain and other effects of treatment, as well as fear of loss of independence, and the basic existential fear of death itself (Antoni et al, 2009; Chida, Hamer, Wardle & Steptoe, 2008; Herschbach et al., 2008; Holland et al., 2013). Van Gruenigen et al. (2010) suggested that anxiety can be more problematic than depression for women with ovarian cancer, but all the above psychological conditions may be more prominent for patients in gynecologic oncology. Often, women with GC do not have as many options to have peer support in comparison with patients with more common cancer types, especially breast cancer, although they often deal with more aggressive treatments than other cancer patients, and often their needs for psychological support remain unmet (Faller et al., 2017; Ferrell et al., 2003).

Moreover, a decrease in the overall QoL is characteristic in women with GC, especially from the time of diagnosis through the completion of their treatment. The physical and emotional domains are affected (Ferreira, Silveira, Gomez, Ruiz, & da Silva, 2015), and a higher incidence of anxiety and depression has been observed in patients undergoing chemotherapy or radiotherapy (Pearman, 2003; von Gruenigen, 2006) whereas breast cancer patients in chemotherapy treatment present with low QoL levels (Mortada, Salem, Elseifi, & Khalil, 2018). A study by von Gruenigen et al. (2010) concluded

that “relatively minor interventions that improve physical symptoms may have large effects on improving other aspects of the social and the functional domains of QoL” (p. 5).

Indeed, emotional distress, anxiety, depressed mood, social disruption, and sleep and fatigue-related disruption as described or reported as phenomena of the psychosocial domain (Antoni, 2013; Ratcliff, Lam, Arun, Valero & Cohen, 2014; Stanton, 2006) and anxiety appears as prevalent in women under treatment, and especially in those undergoing chemotherapy (Lim, Devi & Ang, 2011; Sandadi et al., 2011).

Many authors agree that when dealing with the physical symptoms as a result of treatment, it is equally important that health care professionals also consider the psychological and social aspects of the overall QoL of the patients; providing focused therapy as an emotional and/or social support may also reduce effects on functional and physical domains and vice versa (Coughlin, 2008; von Gruenigen et al., 2009; von Gruenigen et al., 2010). Indeed, research shows that when psychological aspects improve, there is also an improvement in the physiological domain, as the psychological well-being influences the perceived evaluation of symptoms which eventually influences and determines functioning (Anthoni, 2013; Jameson & Von Hoff, 2013; Novack et al., 2007; Würtzen et al., 2015). Also, symptom management seems to presume a positive impact in all domains of QoL (Tabano et al., 2002), an important consideration when designing a treatment plan. QoL as a key-factor for patients during chemotherapy in particular is also discussed by Lauriola and Tomai (2019) in preventing maladjustment, with emphasis on social support and positive thinking coping styles whilst working with the patient individually. As Wenzel et al. (2003) stated, “Caring for the patient, as well as her cancer, requires that measures to preserve or enhance the quality as well as the quantity of life be incorporated into the patient’s treatment plan” (p. 226).

Although QoL and psychological disturbances such as anxiety, depression, and mood have been evaluated in previous GIM/MI studies in cancer, there are no studies on individual therapy with GIM during the period of adjuvant treatment. Hence, overall QoL is one of the variables to be investigated in this study, the second one is its emotional/psychological sub-domain (anxiety/depression/mood), followed by two more QoL factors of fatigue and hope as we will see in the following sections.

1.5. THE SYMPTOM OF FATIGUE

The “symptom” is described as a subjective experience that reflects changes in the bio-psycho-social functioning of the patients, their sensations or cognition (Potvin et al., 2015), and there is a variety of symptoms within cancer care. Symptom management is shown to be the most helpful component gained from psychological support during cancer treatment (Holt, Mogensen, Jensen & Hansen, 2015; Danhauer et al., 2007).

Cancer-related fatigue is defined by the National Comprehensive Cancer Network as “a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (NCCN Guidelines, 2019, FT-1). Cancer-related fatigue has been described as more unrelenting, severe, and distressing because it is more draining, intense, and longer lasting than the usual fatigue experienced by healthy individuals (Holley, 2000).

The literature underlines the importance of the symptom of fatigue, as the most frequently reported side effect of treatment (Arriba, Fader, Frasure, & Von Grueniger, 2010; Broeckel et al., 1999; Ferrel et al., 2003; Dean, 2011; Harrington, Hansen, Moskowitz, & Todd, 2010; Jameson & Von Hoff, 2016; Prue et al., 2006; Ream, Richardson & Alexander-Dann, 2006; Stone & Minton, 2008; Wang & Woodruff, 2015). Fatigue is the most common symptom during chemotherapy (Ahlberg, Gaston-Johansson & Mock, 2003; Morrow, Andrews, Hickok, Roscoe & Matteson, 2001), and might continue up to one year after the end of chemotherapy (Shields et al., 2015).

Most of the studies do not address cancer-related fatigue in a merely physical level. Accordingly, in this study, fatigue will be considered not only as physical but also as a multi-dimensional symptom, as its physical intensity can also compromise psychological or cognitive states of patients with GC (Sekse, Hufthammer & Vika, 2014; von Gruenigen et al., 2009). Fatigue has a profound effect on the whole person with an impact to almost all areas of a person’s life, physically, psychologically, socially, spiritually, cognitively, and in the sense of self (Barsevick, Whitmer, & Walker, 2001; Holley, 2000). Thus, it is multi-dimensional and influenced by various somatic and psychosocial factors (de Raaf, de Klerk and van der Rijt, 2013; Weiss, 2011) and appears to influence the desire to continue treatment (Bower et al., 2006; Alhberg et

al., 2003; Morrow et al., 2001; Sekse et al., 2014). Prue, Rankin, Cramp, Allen, and Gracey (2006) highlight the psychological dimension of fatigue to the physiological one; they describe it as a prevalent issue for this population group regardless of the stage or type of treatment. Moreover, the presence of emotional distress and mood disturbances are often predictors of cancer-related fatigue, second to the type of disease and treatment (Storey et al., 2007). There are some studies indicating a strong association of fatigue and psychological distress (Fabi et al., 2017; Prue, Allen, Gracey, Ranking, & Cramp, 2010), suggesting the need for interventions focused on ameliorating psychological distress in order to reduce perception of fatigue. Thus, many interventions for fatigue in cancer care are non-pharmacological (Dean, 2011).

The increased levels of fatigue in women with GC are well documented, and therefore are providing a motivation to explore this phenomenon as part of this study. Studies on fatigue in breast and GC patients have demonstrated that they experience more severe fatigue compared to patients with other cancer diagnoses (Payne, 2002). Shields et al. (2015) reported fatigue as a ubiquitous symptom in GC and patients receiving increased interpersonal support complain less about it. Indeed, there is an apparent association between overall fatigue in females in gynecologic oncology and psychological distress. The findings by Kangas, Bovbjerg, and Montgomery (2008) and Prue et al. (2010) indicate that alleviating the psychological distress may preempt a degree of fatigue and point to non-pharmacological, effective interventions such as psychotherapy, relaxation therapy, support groups, and listening to music. According to a meta-analysis by Mustian et al. (2017), psychological interventions are effective in reducing fatigue in cancer as opposed to medicine, especially during and after primary treatment. A systematic review (Mitchell et al., 2014) and a randomized controlled trial by Freitas et al. (2012) and Jameson & Von Hoff (2016) reported music therapy as one of the evidence-based psycho-educational interventions likely to be effective in cancer-related fatigue in GC. This supports the intention behind this study that GIM also could have a reducing effect on cancer treatment-related fatigue. This is amplified by the fact that no previous studies on GIM in oncology have addressed directly the symptom of fatigue.

Besides fatigue, psychological needs are equally significant for this clinical population and deserve much attention, as these women are in greater risk of psychological challenges such as anxiety and depression due to the nature of

this cancer type. However, physical and psychosocial domains are often interrelated, and interventions focusing on the physical needs influence the psychosocial domains and vice versa. This fact leads to the next section on the importance of addressing psychological attitudes by boosting coping skills in cancer care.

1.6. “HOPE” AS A RESOURCEFUL ATTITUDE

Hope is another aspect of the psychological domain of QoL of cancer patients that will be explored in this study. In this section, I will discuss the importance of development and presence of coping skills and positive attitudes for cancer sufferers and survivors, essential to deal with the consequences of the disease. There is clear evidence that points to a constellation of factors that predispose individuals with cancer to progress more quickly through its stages. Personality traits, coping styles, levels of emotional expression and self-disclosure, and tendency towards hopelessness and helplessness are amongst these factors, the latter especially related to cancer's outcome (Pennebaker & Beall, 1986; Pennebaker, Zech & Rimé, 2001; Temoshok, 1987; Watson, Homewood, Haviland & Bliss, 2005).

Some researchers have attempted to identify these linkages between the dysfunctional healing system, repressive emotions, and chronic helplessness and hopelessness. This lack of contact with inner resources and creative energy as well as relatedness with others may be products of inability for emotional expression that, in turn, reinforces unconscious helplessness, as the person cannot alter stressful conditions or assert personal needs or rights (Dreher, 2003). Individual psychological reactions and coping strategies such as hopefulness have been found to contribute towards positive health responses to cancer (Coughlin, 2008; Carver, 2005; Felder, 2004; Ferrell et al., 2003; Folkman, 2010). As Folkman stated, “Coping fosters hope when it is at low ebb as well as ways in which hope fosters and sustains coping over the long term” (2010, p. 901). Thus, coping and hopefulness are in a constant, reciprocal, and dynamic relationship, supported by one another.

Hope is important to a patient's sense of well-being and one of the greatest allies that support quality of life (Rosenbaum & Spiegel, n.d.; Rustøen, 1995; Rustøen, Cooper & Miaskowski, 2010). It is a multifaceted and complex concept sometimes difficult to capture in words, and many authors and researchers have endeavored to define (Buckley & Herth 2004; Herth 1990;

Scioli, Ricci, Nyugen & Scioli, 2011; Tsaroucha, 2014). Groopman (2005) described hope as “the elevated feeling we experience when we see—in the mind’s eye—a path to a better future” (p. xiii), providing an introduction to such a deep and multilayered concept. In this study, hope is defined as “a multidimensional life force characterized by a confident yet uncertain expectation of achieving a future good which, to the hoping person, is realistically possible and personally significant” (Dufault & Martocchio, 1985, p. 380). A complementary definition that fits this research is given by Stotland (1969) who described hope as a multi-dimensional process that includes thoughts, actions, and relationships that opt out for a future purpose that has a meaning for the individual. Stotland’s theoretical approach has been embraced mainly by Herth (1990, 1992, 2000) in her work and questionnaire construction for oncology patients, also used later in this study.

Hence, the agent of hope has been identified as an important and effective coping attitude related to positive adaptation and QoL of cancer patients, and an element that helps them in their struggle throughout the cancer trajectory (Herth, 2000). Hope in cancer patients is expressed through a variety of factors, both physical and psychological, including spiritual well-being that is also helpful in fostering hope (Herth, 1990; López & Quinn Griffin, 2009; Tabano, Condosta & Coons, 2002; Visser, Gassen & Vingerhoets, 2010). Hope allows the patients to set new goals when the old ones are no longer attainable because of the disease, and also allows them to find out alternative ways of achieving these, when cancer hinders the possibilities of reaching them through traditional ways (Shorey, Snyder, Rand, Hockemeyer & Feldman, 2002). At the point of diagnosis, hope may focus on cure and meaningful life, and some indicate that this may continue into the advanced phase of illness when hope is seen as a reconciliation and comfort between life and death (Benzein, Norberg & Saveman, 2001; Johnson 2007; Herth, 1990, 2000). Even for advanced cancer patients when “future” is unclear and vague, hope represents the desire for inner peace and serenity towards the “eternal rest” (Herth, 1990, p. 1254). Hence, with such a diagnosis, patients have one additional task: to adapt their hope to new existential uncertainties as they are facing a potentially life-threatening disease (Bushfield & Deford, 2010; Chi, 2007).

1.6.1. REFLECTIONS ON “HOPE”

The information in the section above, helps me as the researcher to formulate part of the rationale of this study, especially the importance of focusing on psychological parameters such as psychological mood and psychological attitudes, such as hope, that work as mediators of resilience to illness. Hope is about making meaning and conveying meaning and hope can be facilitated through supportive, expressive psychotherapies, including psychological, social, and spiritual aspects (Penson, 2007; Teo, Krishnan & Lee, 2019); hence, creating a potential to be explored and resourced via the GIM process. After all, the challenge of dealing with a potential life crisis like cancer, may be seen as an opportunity for people to develop a more intentional way of living, with a clearer focus on their dreams and hopes, with a renewed understanding of their values and appreciation of life (Coughlin, 2008; Ferrell et al., 2003). For these women, developing coping strategies and having a supportive network during this stressful time of cancer treatment is imperative; the work through the instillation of hope that will strengthen and enable them to cope with this difficult situation can be of great significance. This instillation of hope towards an increased resilience can be especially useful for music therapists working with cancer survivors in the acute phase; often, music therapists take a supportive and re-educative role, aiming directly on the physiological effects of cancer treatment as well to address coping skills by acknowledging ambivalent feelings and retrieving inner resources (Allen, 2013).

1.7. INTEGRATIVE MEDICINE AND COMPLEMENTARY THERAPIES

Nowadays, cancer is understood as a multifactorial disease influenced not only by biological heritage, but also psychological, behavioral, and social factors are considered equally important, and more emphasis is given through research and practice (Engel, 1980; Lauriola & Tomai, 2019; Ozcan et al., 2017; Wade & Halligan, 2017). It is a fact that modern cancer care has brought openness to new approaches to integration and holistic thinking (Ben-Arye, Frenkel & Margalit, 2004); there is much room to provide cancer patients with holistic care since treatment decisions are often made first and foremost in relation to the patient’s wellbeing (Cassileth, 2014; Fasching et al., 2007; Ganz et al., 2004; Pichler & Pichler, 2014; Trinkaus et al., 2010).

Integrative oncology uses this knowledge to incorporate non-pharmacological adjuncts into mainstream care to manage physical, emotional and psychological symptoms experienced by cancer patients. There is growing evidence that supports the integration of complementary therapies as part of a multidisciplinary approach to mainstream cancer care (Cassileth, 2014; Society for Integrative Oncology, 2009). According to the National Center for Complementary and Alternative Medicine (NCCAM) “integrative” health care involves a combination of conventional together with complementary approaches in a coordinated way and describes complementary and alternative medicine (CAM) as a cluster of diverse healthcare systems, practices and products that do not usually form part of mainstream medicine (NCCAM, 2008). Hence, integrative oncology refers to the use of CAM (or Integrative interventions-IM) in turn to complementary treatments. Bulfone, Quattrin, Zanotti and Regattin (2009) summarize the reasons: patients wish (a) to be treated in a holistic way (mind & body); (b) to have a more active role in the decision-making about their health; (c) to feel more hopeful; and (d) to improve their QoL in a physical manner, boost immune system, improve symptoms, and prolong their lives. While this is not the current state in the Greek healthcare system yet, the literature on integrative oncology shows that interventions are tailored to patients’ needs, with the ultimate focus on improving their overall health, whereas there are some integrative cancer centers that have incorporated counseling and other methods reflecting a holistic treatment approach (Cramer, Cohen, Dobos & Witt, 2013; Deng & Cassileth, 2005; Deng et al., 2009; Lesiuk, 2015).

As discussed above, because of the complexity of coping with breast cancer and GC, females who experience psychological distress due to their cancer are more inclined to resort to CAM therapies and integrative medicine because of needs that remain unmet within the mainstream medical care (Ben-Arye et al., 2015; Eschiti, 2007; Judson et al., 2011; Lengacher et al., 2006; Magno, Filippone & Scaldaferrri, 2018; von Gruenigen et al., 2006). Nevertheless, despite their common use, many CAM therapies have not been efficiently tested to determine their efficacy, and even less is known regarding their role during chemotherapy or radiotherapy treatment; although there is substantial evidence for randomized trials supporting the use of some mind-body therapies (such as music therapy and imagery techniques) for cancer symptom control (Cassileth & Vickers, 2005; Finnegan-John, Molassiotis, Richardson, & Ream, 2013; Judson et al., 2011; Richardson & Ream, 2013; Fitzgerald & Langevin, 2014), the need for further evidence-based

procedures and establishment of clinical guidelines has been pointed out (Berger, Yennu & Million, 2013; Cramer et al., 2013; Klafke et al., 2015; Magno et al., 2018).

It should be noted here that although we usually refer to CAM altogether, there is a clear distinction between “complementary” and “alternative” therapies. “Complementary” therapies work as adjuncts to mainstream care, comprise supportive measures that assist controlling of symptoms, enhance well-being, and contribute to overall cancer care. Music therapy falls into this category, especially in the mind-body modalities, recommended to reduce anxiety and pain and to improve mood and overall QoL (Boyde, Linden, Boehm & Ostermann, 2012; Cramer et al., 2013; Deng et al., 2009; Stenson & Pejovic, 2013; Teo, Krishnan & Lee, 2019). Hanser (2009, 2016) argued that music therapy and music medicine have roles within the integrative medicine. This is because music can promote expression of difficult feelings, but also can contribute to the development and mobilization of individual’s inner resources and potential strengths, making it possible not only to confront existentially threatening fears but also to promote hope or meaning, also basic principles in GIM, as will be explained below.

1.7.1. PSYCHOLOGICAL INTERVENTIONS

As seen so far, there is substantial body of research and discussion that has been done around the effectiveness of psychological and psychosocial interventions to support their positive contribution medical outcomes in cancer patients. Just as with general medical patients, stress-prone personalities, emotional distress, or poor coping styles increase cancer incidence and mortality and reduce cancer survival. Psychotherapeutic interventions have proven to play a positive role in a better health behavior and biological effects (Andersen et al, 2004; Teo et al., 2019). Promising results show that patients receiving psychotherapy and exposing traumatic events demonstrate positive alteration of immunological markers, can spend fewer days in hospital and medical visits, and finally, drop the overall medical cost of care, implying that they may also be cost-effective (Pennebaker et al. 1988; Watson & Kissane, 2012). Thus, psychological interventions, including creative arts therapies, mainly have been used to reduce negative effects of cancer treatment. Such interventions can promote relaxation and foster healthy states of mind like contentment and hope, and those that encourage emotional expression and sharing can enhance healing (Goldie & Desmarais, 2005; Fawzy, Kennedy &

Fawzy, 1991; Hersch, Juraskova, Price & Mullan, 2009; Langley, Fonseca & Iphofen, 2006; Spiegel, Bloom, Kraemer & Gottheil, 1989; Watson, 2012; Watson & Kissane, 2012). Furthermore, supportive psychotherapy has been found beneficial in promoting positive mental health and overall QoL for women during recurrent chemotherapy treatment (Mukherjee, Mazumder, Kaushal & Ghoshal, 2017). Nevertheless, the review by Hersch et al. (2009) on psychological interventions, including psychotherapy, counseling, relaxation, and other complementary therapies, to improve QoL particularly in GC patients, concluded that there is inconsistency amongst the effectiveness of these interventions in various domains of QoL, mainly due to the variety in the designs of the studies. The authors stressed the need for more research in order to identify the more efficient psychosocial interventions, strengthening the rationale for carrying out the current study.

Jacobsen and Jim (2008) suggested a list of criteria for beneficial psychological interventions in cancer: (a) acceptability to the patients (as measured by drop-out rates), (b) ability to be implemented by a specialist healthcare provider, (c) the approach/intervention in use should be familiar to other mental health providers, and (d) must be generally short-term (fewer than 12 sessions). Watson (2012) added one more parameter: that the primary focus of the intervention should be to increase patients' personal resources in dealing with cancer aspects causing distress, and in this respect, goals for change will be behavioral, emotional, cognitive and interpersonal. Furthermore, Nicholas (2013) argued on another characteristic of psychological interventions: the necessity of the provision for non-specific, supportive psychotherapy, due to the lack of substantial empirical evidence in many clinical situations. Supportive psychotherapy is defined as seeking to help patients deal with distressing emotions, reinforce pre-existing strengths, and promote adaptive coping with the illness (Lederberg & Holland, 2011). Determining the optimal timing for the right psychological interventions and identifying the individuals more at risk for poor outcomes are also important (Antoni, 2013) as are cultural and socioeconomical factors (Couzin, 2007; Lutgendorf, Sood, & Antoni, 2010; Zhang-Salomons et al., 2006). Finally, researchers should encompass a broader range of cancer types, and should understand cancer's effects, stress, and immune response within different cultural and socioeconomic environments (Fagundes, Lindgren & Kiecolt-Glaser, 2013). Since GIM neither has been previously researched with women with GC or patients during active treatment nor has been applied in Greece

within cancer care, these parameters certainly strengthen the rationale of this study in gynecologic oncology in a Greek hospital setting.

1.7.2. THE ROLE OF CREATIVE ARTS THERAPIES

This section is a small prelude to music therapy and GIM within the context of creative arts therapies (CATs). Creative arts therapies (CATs), including music therapy, are frequently described as part of complementary therapies; they are a form of psychological and psychotherapeutic interventions that use the expressive qualities of the creative art to bring about personal change with a goal to increasing the individual's emotional, social, cognitive, physical, aesthetic or spiritual integration and wellbeing during the treatment of an illness or disability (Abrams, 2001; Archer, Buxton & Sheffield, 2015; Bradt, Dileo, Magill & Teague, 2016; Hertrampf & Wärja, 2017; Munro & Mount, 1978). Bradt and Goodill (2013) defined CATs as the implementation of arts interventions by a trained therapist within a systematic psychotherapeutic process, with the aim to address specific issues with tailor-made interventions by means of constant assessment of patient and evaluation of treatment.

The benefits of integrating creative therapies in the treatment of cancer have been substantially documented. There is an increasing number of cancer patients who use complementary/integrative therapies as psychological, supportive therapies during or after treatment to ameliorate symptoms and improve QoL. CATs, including music therapy and its therapeutic approaches in all of its facets, may have an active role mainly within the psychosocial/emotional and physical domains with a gradually growing literature (Boyde, 2012; Burns, Harbuz, Hucklebridge & Bunt, 2001; Nelson, 2017; Puetz, Morley & Herring, 2013; Tascilar et al., 2006; Zhang et al., 2012). There are abundant studies to support the use of CATs specifically in gynecologic oncology in promoting creativity within the healing process, with various psychological and physiological benefits: most of them in breast cancer care (Boehm et al., 2014; Chase, Gibson, Summer, Bea & Alberts, 2014; Gladding & Newsome, 2003; Greenlee et al., 2014; Magill & Berenson, 2008; Monti & Newberg, 2013; Puig, Lee, Goodwin & Sherrard, 2006; Vella & Budd, 2011; Von Gruenigen, Frasure, Jenison, Hopkins & Gil, 2006), and some of them including various music therapy methods and techniques.

More notably, music therapy in various forms has been recognized as a complementary, evidence-based treatment within the medical field and in

cancer care (Archer et al., 2015; Petry, 2006; Puetz et al., 2013; Romito, Lagattolla, Constanzo, Giotta & Mattioli, 2013). It is gradually becoming more popular as a treatment option for cancer patients (Elkins, Fischer & Johnson, 2010) within the category of “mind-body” medicine (Magill, 2006; Tascilar, de Jong, Verweij & Mathijssen, 2006) and has become integral part of the complementary medicine treatment disciplines in gynecologic and breast cancer (Bulfone et. al, 2009; Daykin, McClean & Bunt, 2007; Hertrampf & Wärja, 2017; Loewy, 2013).

Nevertheless, Archer et al. (2015) stressed the need for more exploratory studies in order to establish which patient groups at which stage of cancer are more likely to benefit from CATs and therefore, enhance psychological outcomes in cancer patients. Although there is evidence that there is benefit from the use of CATs, it is still a growing area that can possibly demonstrate more actual effects in various aspects of patients' health. Although there is substantial number of studies in breast cancer, more studies are needed especially in gynecologic oncology, since there is a very small amount of research in this area, particularly studies of the effects of music and its special contribution to this clinical field. This need for ascertainment supports the rationale of this study.

1.8. GUIDED IMAGERY AND MUSIC AND A CREATIVE, PSYCHOLOGICAL THERAPY

The Bonny Method of Guided Imagery and Music (GIM) is an internationally known receptive music therapy model based on music listening in a relaxed state of consciousness while dialoguing with the therapist. It involves elaboration of the patient's experiences and imaging while listening to selective music programs (Bonny, 1997; 2002a,2002b). GIM's protocol consists of a four-step process. During the first phase, the *prelude*, the client discusses with the therapist about the current issues, conflicts or stressors to build up a rapport. In the second phase, usually called *induction*, the therapist provides with appropriate interventions such as breathing techniques or muscle progressive relaxation, to promote mental and physical relaxation. This concludes the therapist's suggestion of an image focus and is followed by the *music imagery* part, in which the client listens to the music and simultaneously describes his/her thoughts, feelings, images or body sensations, whilst the therapist provides with non-directive verbal

interventions, supports, and encourages the client to explore their experience fully. Once the music ends, the session comes to its *postlude* or verbal processing part, where the therapist will help the client to integrate their experience, relate to everyday life, and attribute a personal meaning to it (Beebe, 2009; Bonny, 2002b, 2002c; Grocke, 2005). A simpler form of receptive music therapy inspired by the Bonny method is called “Music Imagery” (MI) and it involves listening to music of shorter duration without interactive guiding and reporting/ processing of the experience afterwards (Grocke & Moe, 2015)

GIM can be considered as a creative, psychological therapy, for it activates inner resources and imagination and focuses on the power of imagery that arises spontaneously in response to a formalized program of relaxation and music to effect personal growth processes in the person (Bonny, 1997). Depending on the phase of the disease, the focus of arts therapies among cancer populations, in general, has been to use the creative modality as a foundation for self-exploration, discovery of meaning, deepening self-awareness, or connecting with own resources, manifesting in a re-conceptualization of one’s life. The structure of music can provide a framework for exploring various areas of the self and thus transform spontaneous and non-purposive expression into meaningful and organized expression through the imagery experience (Bonny, 2002a, 2002b). At the same time, GIM also facilitates opportunities to focus on healthy aspects of the psyche, searching inside for resources to engage in the disease process (Summer, 2011). Batt-Rawden, DeNora, and Rudd (2005) argued that contact with music reconfigures body and self in relation to ways of “being” and “doing” away from illness and despite the illness, thereby focusing on the healthy part of the individual. By doing so, life makes sense and meaning in a personal space previously disrupted by illness and disease (Aldridge, 2002), basic principles also in GIM theory and praxis. Bonny (1997, 2002c), as founder of the method, acknowledged GIM for its “holistic” effect, and together with its modifications it has been found effective in addressing a variety of psychological or physical concerns, as medical populations have been found to gain benefits from it, including people with cancer, as seen below. Hence, the conceptual framework that guides this study is based mainly on humanistic, integrative, and holistic aspects of GIM, where the strength comes from the “inside” of the individual (see Article 1 for details on the theoretical principles of GIM).

1.8.1. OVERVIEW OF GIM AND MI METHODS IN CANCER CARE

This section is a review on GIM's literature in cancer care which is gradually growing. GIM within the medical context has been introduced by many authors and GIM clinicians. Justice and Kasayka (1999) present GIM in a holistic, integrative context, and attribute its impact mainly to the fact that the way music is used in the process helps patients access their own internal, intuitive resources that can be recruited to gain healing power and insight. The authors highlighted the usefulness and benefits of GIM in short formats, as they require less energy and help maintain a singular focus. A few authors highlight GIM developments and discuss the advances of its use in medical populations, including cancer and introduce adaptations and modifications of the original method to address the specific needs of various clinical conditions with powerful effects on both psychological and physiological domains (Grocke, 2010; McKinney, 2002; McKinney, Antoni, Tims, Kumar & McCabe, 1997; McKinney & Grocke, 2016; McKinney & Honig, 2017). Short (2002; 2016) suggested that GIM with medical patients aims at decompressing of emotions and gaining insight of problematic areas of negative behaviors and patterns and improving self-concept. It also involves the symbolical transformation of body parts and increased feelings of mental and physical health.

There are quite a few reports on the use of GIM in cancer in case studies, anecdotal reports, and research, some in the classic Bonny Method GIM form and some in modified versions. These reports focus on restoring physical and psychological wounds through a process of grief and development of trust (Hale, 1992), alleviating pain and work on identity, psychological, and spiritual aspects in palliative care (Marr, 1998-1999), psychosocial and existential issues and traumatic memories (Cadrian, 2009), and work with a patient's experience across the whole cancer trajectory consisting of both full-length and shorter, modified GIM sessions and her key themes (McDougal Miller, 2016). McDougal Miller emphasized the multi-dimensional process that impacted the client on emotional, mental, physical, spiritual, and relational levels.

A few research studies have also been discovered in the GIM literature. Burns (2001) reported results of an RCT that found benefits of GIM on mood and QoL in eight women cancer survivors after they finished active treatment. The patients in the GIM group were provided with a series of 10 weekly, individual

GIM sessions and reported significant improvements in mood, tension, fatigue, and confusion, and some positive changes in anger and depression. The positive tendency in improvement for anger/hostility and tension/anxiety maintained in the 6-week follow-up, with the experimental group also reporting a higher QoL at post-test and follow up compared to the control group. After informal imagery content examination, Burns suggested more emphasis on spiritual and existential aspects that seem crucial to cancer patients and pointed to the need for more clarification on the clinical protocol regarding appropriate GIM session timing and dose. Another study in cancer (McKinney, Clark, Kumar, Antoni, & Kumar, 2011) investigated the effect of six biweekly individual GIM sessions in 10 women recovering from non-metastatic cancer on distress, overall QoL, and relevant endocrine markers. The women reported reduced depressed mood and total mood disturbance, increased emotional and social wellbeing, decreased intrusive thoughts and avoidance behaviors. However, in contrast to Burns' study (2001), the results were not sustained at the 6-week follow-up.

Bonde (2005) performed a study to investigate the effect of 10 individual GIM sessions on six women, all cancer survivors. The author observed no significant alteration in depression, although anxiety was significantly reduced, and no significant pre-post change for QoL. The imagery was meaningful for the women, not specifically relevant to cancer, but rather to a more general process of self-understanding and coping during the period of transition to normal life (Bonde, 2005, 2007). Bonde found the number of minimum 10 sessions consistent with previous literature by Burns (2001) and the GIM in cancer as beneficial. Five out of six participants of the study assumed they would have benefited from GIM if they had tried it earlier in their therapeutic process, after diagnosis or during treatment; if so, they suggested GIM of shorter duration with "easier" music and emphasis on anxiety and stress management, comments that provide with a good motivation and framework for the current study. Suggestions for flexibility of session appointments according to clients' need were also pointed out by Bonde, the need for control group and larger-scale efficacy studies, as well as the need for investigating the effect of GIM in different cancer types and specific phases of cancer treatment.

Zanchi, Bonfiglioli, Nicoletti, and Bitti (2016), researched the effects of a series of eight GIM sessions in 16 cancer survivors. According to the published

abstract, GIM was found beneficial in all aspects of QoL and mood of the patients, who reported the experience as supportive and helpful for them.

As seen below, most of the literature in cancer care concerns modified GIM and MI or group GIM and MI. Allen (2010) investigated the effects of group music psychotherapy (group Music and Imagery-GrpMI) on adaptation and changes of identity and social self-concept, body image, self-esteem and role performance for breast cancer survivors. The research comprised of two groups randomly assigned; one received GrpMI, and another group received cognitive-behavioral support, both for 10 weeks. Although positive outcomes occurred in both groups, GrpMI had a more significant effect on the personal identity, self-esteem, role performance, and body image, but not academic/work and social domains. The most important finding was the improvements of self-concept, since this is a major concern for women with breast cancer after mastectomy.

Dimiceli-Mitran (2015) described her protocol of six group meetings with cancer survivors at an outpatient center, based on the model of MI combined with a model for group work introduced by oncologist Carl Simonton. The model is called “focus on wellness,” and the music is shorter and simpler in dynamics than in GIM, with holding and grounding qualities. The groups address common issues along the cancer trajectory, empower members by introducing a proactive wellness survivorship approach, access resources and skills for self-care, and facilitate sharing and connection.

MI applications have also been used to explore the effects for women with cancer in gynecologic oncology. Wärja (2018) explored “Brief Music Journeys” (KMR in Swedish) for women recovering from GC, in a combination of individual and group sessions, including art making. The research indicated that this form of versatile, modified form of GIM comprised of 2-8 minutes of music could be very useful in individual and group psychotherapy in hospital settings, to address a variety of needs, crisis conditions or interpersonal problems. Another study has been delivered by Hertrampf (2017) and concerns the application of GrpMI for females with breast and gynecologic cancer undergoing chemotherapy or outpatient palliative care. The groups ran for 6 weeks, exploring patients’ experience on the role of music, role of imagery, the role of the group setting, and pivotal moments of the overall experience. The author suggests GrpMI as beneficial for helping women reconnect with personal resources and empower them to deal with cancer

treatment and also assist them in integrating of a new body and self-image, as they come to the rehabilitation phase. Patients reported changes in behavior, communication, and perception of cancer, all important elements to be taken into consideration in relevant future studies.

Meadows (2015) described his clinical and theoretical protocol with MI in outpatient cancer care. His model of using MI interventions involves more clearly working with patients during active chemotherapy treatment. His work consists of three levels: (a) symptom management where the focus of MI is to help the patient deal with experience of anxiety and symptoms on a physical level, (b) supportive music therapy that is mainly treatment-focused imagery, and (c) the reconstructive MI, which is primarily a reflective period that provides space for giving meaning to the cancer experience. In conclusion, Meadows highlights the MI's capacity to help in different levels, addressing physical, psychological, or even deeper existential issues: "Connection between inner work and outer lives can, correspondingly, be seen in different ways" (p. 197).

Burns et al. (2008) reported a feasibility study of possible benefit of MI methods with patients with acute leukemia receiving intensive chemotherapy. They found that although there were benefits and improvements on QoL aspects, patients with lower baseline distress may have more benefits including lower distress rates at discharge. It may have been more difficult for patients with higher distress rates to engage in MI interventions without the presence of a therapist, suggesting that structured, therapist-led interventions may provide more support for these individuals.

A few interesting considerations related to receptive music therapy and MI interventions have been reported in the two following studies: Burns, Sledge, Fuller, Daggy and Monahan (2005) found out that cancer patients are keen on music interventions during treatment, with a preference for receptive music approaches instead of interactive music playing, which supports the current study. Taking a step further, Burns, Meadows, Althouse, and Perkins (2018) compared music listening with MI approaches. The authors agreed with Meadows (2015) that supportive MI is effective in treatment-focused sessions in order to prepare patients manage their chemotherapy sessions in a better way and reported that patients in supportive MI sessions engage more emotionally in the experience, replenishing resources by activating positive coping mechanisms; however, such broad emotional experience also

contains higher level of distress, highlighting the importance of the monitoring role of the therapist to constantly modulate and accommodate the process in response to the patient's emotional needs. This also suggests that MI might have more benefit if applied in short-term treatment (1-3 sessions) as a preparation for treatment as opposed to preferred music listening which usually involves a narrower and therefore "safer" emotional experience.

To summarize, considering GIM as a mind-body therapy, the literature suggests it has the potential to contribute positively to diverse aspects of a person's health via its powerful components; imagery contained by the music has the potential to be a powerful source of insight and expression of life issues, as well as to offer a creative path that sustains life energies. The process of creating meaning—an important element in cancer psychological care as seen from previous literature—can be supported by positive images elicited with music as an emotional container. Thus, GIM can meet the needs for emotional processing through the expression of feelings and coping with emotions both in symbolic and verbal language. Subsequently, as an intervention promoting focused expression on emotions, this may lead to a reduction of medical symptoms and a better sense of well-being (Monti et al., 2006; Stanton et al., 2000).

GIM may as well promote physical relaxation. This is an essential element for the symptoms that patients encounter, such as the fatigue and exhaustion experienced as a result of chemotherapy or radiation treatment. Through appropriate use of music and relaxation induction, GIM may well serve to facilitate these needs for somatic relief. This is consistent with McKinney and Grocke's (2016) review on GIM in medical settings in which the authors concluded that GIM has powerful benefits in both physiological and psychological levels. Meadows (2015) also described GIM with a focus on integrative, holistic care; GIM can serve both as a supportive adjunct to chemotherapy but also as a psychotherapeutic method working with challenges related to the experience of cancer.

1.9. RATIONALE OF THE STUDY

All the knowledge and information acquired from the literature review section can give some essential directions towards the formulation of the rationale of this study. Taking into account all the evidence provided, GIM and its adaptations and modifications have proven efficient and useful in working with

cancer patients, improving various physical, emotional, existential, spiritual, or relational aspects of patients' lives. Hope is an essential attitude and important agent in cancer survivorship, and it can be reached through supportive psychological therapies that facilitate meaning-making and elicit resources for the patient. The literature also underlines the importance of fatigue, another aspect of QoL that can also be affected by psychological interventions. This interplay between specific QoL factors, especially the two-way relationship between mood and the physical symptom of fatigue and the parallel importance of the development of coping strategies via agents such as hope, set the challenge of exploring those factors within a psychological perspective. Therefore, the rationale of this study is based on the need to explore the role of GIM as psychological, supportive therapy in cancer care on important dimensions of the patients' health, namely, overall QoL, and aspects of QoL, such as mood disturbances, fatigue, and hope. The last two factors have not been directly addressed and systematically explored previously in the GIM literature.

There is a fair amount of reports about GIM in cancer care. However, although GIM has been applied to cancer patients and survivors in many different modified forms, as seen from the literature review, there is a gap in applications with regards to the effect of individual GIM sessions during the period of active, adjuvant treatment in gynecologic oncology or other cancer types. Most of the studies have been applied to the rehabilitation phase, in palliative care, or even in the treatment phase; however, they have employed only modified MI or group forms of GIM. There are no previous studies exploring the potential of GIM in a series of a one-to-one therapy during cancer treatment, a fact that supports the originality of this study. Considerations and practicalities about working with a challenged group of patients during their chemotherapy is another aspect that should inform the feasibility of this project.

The rationale to implement this project is amplified by the extra challenge of developing and promoting a GIM therapy model where sensitive issues for these women can be expressed, addressing women's needs within a context of their health belief systems, cultural burdens, and supportive care concerns, while keeping to a rigorous approach to scientific methodology. It may be well questioned (a) whether Greek patients in active treatment for cancer will respond to the invitation to participate in an unfamiliar psychological intervention never offered previously by their medical carers, (b) whether they

can sustain the process and dynamics of a series of GIM sessions, and (c) whether there is eventually any benefit from it. In this context, the study seeks to explore how the GIM experience is perceived by Greek women as there is no previous reference to this regard.

Finally, although many patients resort to CAM therapies, there is often a lack of information in the medical staff about their efficacy (Chase et al., 2014) and this is certainly true for the majority of the Greek medical settings that do not usually provide any form of complementary or psychological therapy. Schofield, Diggins, Charleson, Marigliani and Jefford (2009) suggested the development of evidence-based guidelines to assist oncology health professionals to have respectful and balanced views on CAM therapies alongside cultural considerations and thereby bridge the communication gap with patients who use them. Under the circumstances, introducing a complementary therapy within such a context is one more challenge for this study, regarding the potential recognition of the efficacy and effectiveness of psychological therapies in specific aspects of gynecologic oncology patients' general quality of life by the Greek medical staff and service providers in the future.

CHAPTER 2. METHOD

2.1. PURPOSE OF THE STUDY, AIMS, AND RESEARCH QUESTIONS

The overall purpose of this investigation is to explore the potential of the GIM as supportive psychological intervention for women in an outpatient gynecologic oncology unit undergoing active, adjuvant treatment in order to help professionals, clinicians, and researchers develop their understanding of working mechanisms and benefits of GIM as a model of receptive music therapy, and encourage further research in oncology with various cancer populations and stages of the cancer trajectory. The design of this project has two parts, consisting of a feasibility study, followed by a pilot randomized controlled trial (RCT).

The purpose of the first part, the feasibility study is (a) to determine the potential and impact of a series of six individual GIM sessions as a psychological supportive therapy for females with first diagnosis or metastatic GC, during the same period as their chemotherapy treatment and (b) to investigate how a medical setting such as a Greek hospital can make use of GIM to facilitate or enhance treatment outcome in GC in the period of active treatment. The feasibility study has the following main aims:

Aim 1: To determine the feasibility of GIM as a psychological intervention for women with GC during the course of active treatment for cancer in a Greek hospital.

Research question 1.1.: Is GIM viable in a Greek hospital setting regarding key processes, resource assessment, and management assessment?

- a. What individual and structural factors may influence the feasibility of GIM in women with GC in a Greek medical setting?
- b. How can GIM be more efficiently integrated into the Greek medical setting and treatment model?

Research question 1.2.: What is the suggested clinical protocol of a series of short GIM sessions with women with GC regarding:

- a. Intervention protocol
- b. Music
- c. Appropriate evaluation/assessment tools

Aim 2: To explore GIM's usefulness and potential effectiveness at improving aspects of QoL amongst women with GC during treatment in a preliminary level.

Research question 2: Is a series of short GIM potentially effective for:

- a. Decreasing anxiety levels in women with GC?
- b. Decreasing depressing levels in women with GC?
- c. Improving the general QoL of the participants?
- d. Reducing the symptom of fatigue for these women?
- e. Increasing the sense of hope for these women?

Aim 3: To discover the perceived impact of GIM for the female participants.

Research question 3:

- a. How do participants describe their experience regarding motivation, expectation, tolerance, and preferences with regard to GIM?
- b. What do participants find significant and meaningful in GIM?
- c. What are the participants' suggestions towards the improvement of GIM's procedure within the hospital setting regarding their availability, treatment burdens, and their physical condition?
- d. Did participants perceive GIM as influencing QoL aspects such as mood and anxiety, levels of fatigue and hope?
- e. Are there any other prominent needs of these patients that can inform GIM practice in a better way?

Thus, the feasibility study seeks to explore whether shortened GIM sessions may contribute to better overall QoL, help decrease anxiety, depression, and the symptom of fatigue, and encourage the development of coping attitudes such as hope. The formulated directional hypotheses are:

- 1) Patients who participate in six individual supportive GIM sessions during active treatment for GC will report improvement in their overall QoL levels as compared to pre-treatment as measured by the *Functional Assessment of Cancer Therapy-General* (FACT-G).
- 2) Patients who participate in six individual supportive GIM sessions during active treatment for GC will experience decrease in depression and anxiety levels as measured by the *Hospital Anxiety and Depression Scale*.
- 3) Patients who engage in six individual supportive GIM sessions during active treatment for GC will report an improvement in their levels of fatigue and hope as measured by two 10-point Likert Scales.

For the second part of this investigation (the RCT pilot), questions, variables, procedure, and design will be evaluated and constructed according to the feasibility study's outcomes and pointing directions so that it will inform the parameters that need to be adjusted for the RCT pilot. Should findings of both studies confirm that GIM is a feasible intervention and therefore could be an effective treatment, this knowledge can inform clinical practice and give suggestions for a large scale RCT protocol. The preliminary information of feasibility aspects and design that can be obtained from the two parts of this investigation is shown in Table 2-1 below based on Abbott (2014), adapted for the needs of this project.

Feasibility study objectives to determine	Pilot trial objectives to assess
<ul style="list-style-type: none"> • Access to participants (e.g. willingness of clinicians to recruit, response to advertising, proportion of respondents who meet eligibility criteria) • Barriers to participation • Feasibility /suitability of assessment procedures and outcome measures • The necessary time and resources required to conduct assessments • Willingness of participants to be randomized to the proposed treat • Whether a complex treatment is deliverable in clinical setting • Barriers to delivery of intervention in the health care system • Clinicians' adherence to protocols • Patients' acceptability of treatment/ adherence to treatment • Appropriateness of target group for intervention • Multicenter / multisite issues 	<ul style="list-style-type: none"> • Whether recruitment works well • Recruitment rates per week/month • Willingness to be randomized to the proposed treatment group • Randomization processes working smoothly • Effectiveness of blinding • Capacity/resources to conduct all trial processes • Access to equipment, space, personnel time • Processes to ensure/audit treatment fidelity • Adequate time, intensity, frequency, and effects of intervention • Assessment processes are timely and complete • Participant retention amongst the allocation groups • Data completeness • Whether treatment effects are consistent with expectations/previous literature • Challenges faced by site, personnel

Table 2-1. Objectives of the two preliminary studies (Adapted from Abbott, 2014)

2.2. ONTOLOGICAL AND EPISTEMOLOGICAL UNDERPINNINGS

Music therapy and GIM are not incorporated in the medical setting in Greece, and this is the first time that GIM will be implemented as a novel intervention in a Greek outpatient oncology department with a Greek population. Also, individual GIM during active cancer treatment has not been reported in the literature before. Therefore, the first part of this investigation is a preliminary feasibility study, with considerations to the broader cultural, economic, and socio-political context that shapes this healthcare experience, and evaluation of this reality as a product of human activity. Acquiring new knowledge and understanding of this clinical reality can assist in the promotion of improvements in GIM procedures and psychological interventions in the Greek healthcare system and in general.

The overall design of this two-part project is an exploratory investigation, conducted for a condition that has not been investigated clearly enough. The investigation intends to establish priorities and develop operational definitions and strategies, thereby helping to improve and determine the best final research design (Shields & Rangarajan, 2013). In this two-part project, different designs and types of data are being used according to the separate parts of the research as each part of the overall project has particular aims and concerns (Brannen, 2005). There are both qualitative and quantitative data to be analyzed in order to determine whether the design of the research investigation and the application of the intervention are feasible and worked as intended.

In order to get an understanding of the feasibility questions, data for the first study are collected from different, quantitative and qualitative sources: observations, notes, patients' experiences and questionnaires. This includes data that need to be evaluated in a qualitative, descriptive way and quantitative data on psychological and physical effects. To reduce bias, quantitative data from the questionnaires' scores are collected first, followed by qualitative, subjective data derived from participants' interviews, in order to explore how GIM is perceived and how it affected the participants in various ways.

Hence, the feasibility study is a mixed-methods investigation. Because of the multi-faceted nature of cancer needs and the divergent range of patient preferences, mixed-methods designs can provide a more in-depth

understanding as to whether, how, and why certain approaches might be more beneficial (Bradt et al. 2016). A mixed methods design has been recognized amongst the major research approaches (Johnson et al. 2007; Sosulski & Lawrence, 2008) and is a synergetic model that integrates a combination of quantitative and qualitative research methods represented by different procedures for data collection and analysis (Borkan, 2004; Mertens & Hesse-Biber, 2013), thereby strengthening the validity and reliability of a study. Such methods are best used to take a complementary look at both breadth and depth, that is, at both causality and meaning (Coolican, 2014; Nastasi et al., 2007).

With a mixed-methods design, it is possible to explore development, meaning, and understanding of the implementation of GIM as an intervention for women in a gynecologic oncology setting (Burns & Masko, 2016). This design will address the feasibility study's questions at different levels, qualitatively and quantitatively, so that "potential participants and practitioners are actively involved in the research to assess the feasibility of an intervention and to ensure a good intervention-context fit" (O'Cathain et al., 2015). Moreover, "the combination of self-reports and qualitative interviews gives the participants the opportunity to formulate their critique and ideas and the researcher an opportunity to elaborate his/her own understanding of the issues and concepts operationalized in the questionnaires" (Bonde, 2015, Discussion, para. 5).

Finally, the feasibility study is an embedded design where a single data set is not sufficient since each type of question requires different type of data. In this study, I embed a quantitative strand within a larger qualitative design (Creswell & Plano Clark, 2011). The purpose is to answer different types of questions so as to collect information at various levels and test instruments that can be later used in a quantitative phase (second part as an RCT pilot), to determine the processes, to explore and assess relationships or identify new variables, and to develop theoretical framework or re-consider design and instruments, when needed.

Within this context, for the second part of this project, quantitative methodology has been used to investigate the suitability of tools to detect possible changes in an RCT study and preliminary effectiveness of GIM in this setting. Data and results from the feasibility study are used to contextualize and plan the second, experimental study (RCT pilot) using objectivist methods. The quantitative data collected from the second part of the study

can shed light on the results of the first study and suggest a firmer, larger scale study (Bradt, Burns & Creswell, 2013; Creswell & Plano-Clark, 2011; Hanson, Creswell, Plano-Clark, Petska & Creswell, 2005; Magee, 2016; Tashakkori & Creswell, 2007). Although the feasibility study results are not aimed at validating the results of the second study directly, they will help the emergence of new or modified research questions arising during the phase of design, data collection, analysis, or interpretation (Plano-Clark & Badice, 2010).

The RCT pilot study will be a fixed design, involving two conditions (GIM and treatment as usual) in parallel groups, with the intention to measure the effect of GIM (performance numeric data) according to the predetermined instruments chosen for the study questions emerged from the feasibility study (Creswell, 2003). More details on the design of the quantitative part of this study and the full protocol will be presented later in this thesis and also in Article 3.

Qualitative and quantitative data from the two parts of this preliminary project are being reported separately according to the nature of each research question and will be connected and integrated during the interpretation of the entire analysis, as they complement each other (Sale, Lohfeld & Brazil, 2002). In this way, collection of different forms of data that answer the basic essence of what, how, and why GIM as an intervention in GC and breast cancer will work according to the issues laid out in the research questions (Bradt et al., 2015). Employing this design allows the researcher to get a fuller understanding of the usefulness of GIM in gynecologic oncology that may be changing as a result of being studied (Hanson et al., 2005).

The use of different methodological approaches in the same research project may evoke various epistemological or methodological problems. In my understanding, the knowledge provided by self-reported questionnaires and the knowledge derived from the interviews are different in nature and could not have been obtained otherwise. Results from these different sources, provide information that allow one to compare and dialogue on processes, feasibility, and outcomes, even when it is not possible to generalize the results. Although the quantitative and qualitative analyses have been carried out according to separate scientific methods-guided by the wish of finding answers by combining different stances- I choose the paradigm of pragmatism as an “umbrella paradigm” as explained in the next section (Creswell & Plano Clark, 2011).

2.2.1. PARADIGM

The approach in this study is underpinned by a pragmatic philosophy that draws from the advantages and strengths of both quantitative and qualitative approaches (Mertens, 2005; Johnson & Onwuegbuzie, 2004). Pragmatism deals with consequences of actions. It is problem-oriented, pluralistic, real world practice-oriented and provides the underlying philosophical framework for exploratory research, which this study is (Mackenzie & Knipe, 2006). Considering the background and aims of the project, a pragmatic research paradigm is appropriate because it focuses on the “what” and “how” of the research problem and allows for acquisition of knowledge through the combination of action and reflection (Biesta, 2010; Thorpe et al., 2009). The pragmatic paradigm places “the research problem” into the “center” and applies different approaches to understanding it (Creswell, 2003, p. 11). In this way, data collection and analysis methods are chosen as those most likely provide insights into the research question with no philosophical loyalty to alternative paradigms. Furthermore, pragmatism acknowledges “the existence and importance of the natural or physical world as well as the emergent social and psychological world that includes language, culture, human institutions, and subjective thoughts” (Greene, 2007, p. 83) and knowledge is viewed as being constructed yet based on the reality of the world we experience and live in. Pragmatism endorses eclecticism and pluralism; for example, different theories, and perspectives can be useful, as well as observation, experience, and experiments as ways of gaining an understanding of people and the real-world phenomena. It endorses a strong and practical empiricism as a way to determine “what works” and which action to take as a next step (Johnson & Onwuegbuzie, 2004) with respect at “the influence of the inner world of human experiences in action” (Frels & Onwuegbuzie, 2013, p. 186).

Although I had not previously delved into the details of pragmatism as a philosophy, I am choosing the paradigm of pragmatism as it feels more appropriate for the purpose of the study. It allows me to gain knowledge towards the desired ends by permitting the influence of my personal values when possible and exploring the relationships in the research and what is appropriate according to my views. Pragmatism allows me to match different methods to specific questions and purposes with flexibility while I work amongst various methods involving qualitative and quantitative data, considering ontology and epistemology of qualitative and quantitative

research perspectives within the same continuum rather than as a dichotomy seen in more puristic positions (Mertens, 2005). I consider real-world research as multi-paradigmatic with many ways to answer a question amongst the research cultures of social, natural, and humanistic sciences (Robson, 2002).

2.2.2. BIAS AND PRE-UNDERSTANDING OF THE STUDY

In a research context, it is essential to acknowledge any possible biases and to try to work together openly with that knowledge. Blocked pre-understanding creates bias and blocks innovation and creativity. One must stay open, aware, and pragmatic in order to improve procedures and processes in a study, especially when it involves qualitative inquiries open to flexible interpretations. Findings of the qualitative inquiry of the project are the intersubjective product of the researcher and the research and reflexivity is important in overcoming my own bias, which is to accept my own subjectivity in this process. Every researcher has their own values, beliefs, and views, but they should try to collect, analyze, and interpret data as impartially as possible. The researcher needs to be explicit, critical, and faithful at different phases of the inquiry process (Zohrabi, 2013). However, this is not always easy, since I am a GIM therapist and trainer and developing a new field of work in GIM is amongst my interests. I acknowledge the fact that I need to remain as nonjudgmental and clear as possible throughout the research process by upholding the ethical principles, performing the evaluation as accurately as possible, and reporting the findings honestly.

It can be questioned that the researcher being as well the therapist may influence neutrality; the dual role may influence women's responses unconsciously or consciously and may influence the result and understanding of the inquiry. Especially for the second study (RCT pilot), I must acknowledge my own biases and the possible influence on outcomes (see also Article 3). To protect my bias due to my own pre-understanding, my position for this study remains in the role of the principal investigator. The GIM sessions were conducted by other GIM therapists, thereby minimizing problems of neutrality deriving from my dual role. To assign roles and tasks, I have used peer debriefing with a small team of colleagues asking for feedback and have requested guidance from my supervisors. Nevertheless, as the first GIM therapist and the only trainer in the country, my only choice of GIM therapists were former students of mine. This was a pragmatic consideration that may

cause limitations in terms of bias. However, at the same time, it ensures that all therapists have similar standards, style, and quality of working, as they all have been supervised by me and maintained good rapport with me throughout the project. Adherence and treatment fidelity were monitored thoroughly by using forms and logs completed by therapists at each session.

Involvement of my own pre-understanding and meaning system cannot be totally avoided particularly for the qualitative part of the study, as I need to use a considerable amount of personal, qualitative judgment, and interpretation of the study data (including formulating questions, decisions on method and tools, etc.).

Blinding is also a factor for reducing bias because blinded clinicians are much less likely to transfer their attitudes to study participants or to provide differential treatment (Karanicolas et al., 2010). However, in this study, it is not possible to achieve full blinding because of the multiple coordination between myself, the therapists, the physicians, and the nursing staff. However, blindness will be ensured as far as possible by coding of the data and replacing names with numbers. Also, participants and health providers (the medical doctors of the department) were masked in the second part of the study (see Article 3; Gul, 2016; Viera & Bangdiwala, 2007).

I have conducted post-therapy interviews and remained the main study coordinator and supervisor of all stages of the research process. In the position as an interviewer, I was aware of the need to be detached from prior therapeutic experience, own knowledge, and beliefs and to let go of my personal agenda that may influence the qualitative data, so that I would achieve a phenomenological perspective from the participants (Roulston & Choi, 2018). In any case, I was blinded to the contents and participants' personal experiences until the interviews. This helped to enhance neutrality and openness, though at the same time, my knowledge of GIM allowed me to follow up and go deeper in the interviews.

However, to facilitate the relationship with the interviewer and establish rapport (Liamputtong & Ezzy, 2005) that is essential for interviews with sensitive content involving discussion on an intimate and taboo topic (Dempsey, Dowling, Larkin & Murphy, 2016; Renzetti & Lee, 1993), all participants had the opportunity to meet me in advance as I introduced myself

as the main researcher, conducted the initial intake and informed them about my role as an interviewer at the end of the GIM sessions.

As the principal researcher, I am completing this project as part of my PhD training, and I anticipate it will give me the basic knowledge and qualification as a scientific researcher. I cannot deny personal bias towards the study, since I believe in the power of music and GIM; therefore, findings of this study could possibly affect me in terms of professional or financial status. If findings of this study are encouraging, the study may also serve as a platform from which I may conduct further research and improve research expertise or enrich current clinical practice (Aldridge, 2000). I also understand that cognitive bias should be avoided in case of conflicting results. Negative findings may still benefit the scientific community, as they will inform why the specific intervention has failed, or what improvements may be considered in the future.

2.2.3. PERSONAL STANCE

My beliefs and attitudes as well as my theoretical orientation have certainly influenced this endeavor. My relationship with music has been developed through a very personal process since I was a child. I believe in the power of music as it has been a companion to my own personal journey, my own reflections and life transitions, and led my decision to become a music therapist. Later in my life, I became fascinated by witnessing the transformative experiences of my clients when using music in my clinical work, not only for its communicative and expressive capacities, but also for the symbolic associations that could arise in therapy and for its effect in so many different levels of the human existence, body, and soul.

My personal assumptions and previous observations about music which were carried forward to this study, are that cancer sufferers can also use music and the experiences generated within a GIM context as a vehicle for their own personal journeys. Music is a universal medium that can always be contextualized in different cultures including clinical populations (Darnley-Smith & Patey, 2003). I believe music may be reflective and resourceful in such a difficult journey through the cancer trajectory, providing a possible new way of relating, engaging with emotions, and coping through one's own resources.

Music has been imbued with therapeutic, curative, and other medical value over the history. Nowadays, the relationship between health and music has been explored extensively, with growing evidence of the use of music as a health resource (Ekholm & Bonde, 2018; McDonald, Kreutz, & Mitchell, 2012). I see health as a continuum of the human existence that it is not defined solely by the absence of disease. I perceive health as influenced by us, by activating internal psychological resources to help us cope with the adversities of illness, and I believe that music can certainly assist these processes.

I have experience in the music therapy field for at least 20 as a clinician, a supervisor, an academic lecturer, and a trainer of the GIM method. My theoretical framework derives from the psychodynamic and humanistic schools of thought, and my clinical practice is based on interactive as well as receptive models and approaches. However, this expertise in different models, the diverse angles of my supervisors over the time, as well as my clinical and teaching experience in various countries, in different cultures, and with different clinical populations have allowed me to think in a flexible and inclusive way, by combining approaches and "out of the box" thinking.

This flexibility and openness have been essential in my role as a clinician and GIM supervisor in the field of oncology over the last 10 years. These qualities help me in dealing with all the barriers and arduousness across the orbit of treatment, especially in a cultural context where cancer is treated as a taboo and patients require space and time to open up and accept. Working across the cancer trajectory in groups or individual therapy requires ability to adapt to various needs of patients with different diagnoses, either in various stages of treatment or in the rehabilitation phase. I have learned to acknowledge the impact of the disease on the individual and how this affects the person's relationships within the cultural profile of our society. I have learned to respect individual reactions and differences while coping with cancer, including personal integrity, beliefs, and values and encounter them with patience and empathy.

I believe these characteristics have helped in formulating my newer role as a researcher, by allowing me to consider carefully all aspects of this research, clinical considerations as well as possible inhibitory factors along the way. These qualities have also helped me to provide practical guidance and insightful supervision to the GIM therapists who led the therapy sessions of

this study. In this study, I operate from a client-centered, resource-oriented, humanistic theoretical orientation that helps patients towards self-actualization and fosters positive experiences (Jones-Smith, 2016). The humanistic approach is also compatible with GIM, as it is one of the main traditions that have built upon its practice and thinking (Bonny, 2002a; Bruscia, 2002). Yet, I acknowledge the fact that authentic difficult feelings may also arise, and these should not be rejected or overlooked, but instead be embraced and explored with empathy and compassion, if needed.

2.2.4. THEORETICAL FRAMEWORK

In order to integrate my views into a single approach, I have chosen the theoretical framework of psycho-oncology for this study because it deals with the psychological reactions and the behavioral components that come as a result of the experience of cancer and acknowledges the multiple dimensions of treatment symptoms (Lang-Rollin & Berberich, 2018). The principles of psycho-oncology contribute to my holistic understanding of cancer as a mind-body interaction with a focus on multi-dimensional aspects of quality of life and well-being within a humanistic approach. In this study, I see GIM within the context of supportive psychotherapy, which is a psychological treatment model of psycho-oncology (See also Article 1).

2.2.5. ETHICS

This investigation (both parts) was a collaborative research project in cooperation of the Doctoral Program in Music Therapy (Department of Psychology and Communication) of Aalborg University, Denmark, the Aretaeio University Hospital that specializes in Surgery, Obstetrics & Gynecology, and Radiology (University of Athens, School of Medicine), and the non-profit organization “Sonora-Interdisciplinary Organization for Music Therapy & Research” based in Athens, Greece. The research was carried through according to the ethical standards of AMI and the National & Kapodistrian University of Athens (School of Medicine). All procedures of the study protocols were reviewed and approved by the Ethics Review Board of Aretaeio University Hospital, in Athens, Greece, with protocol numbers EE-2/01/31/1/2017 (feasibility-Appendix A) and 62/19-06-18(RCT pilot-Appendix B).

Participation in both parts of the investigation was in a voluntary basis, and no identifying information or other factors that compromise participant privacy were included in the study data. Participants signed informed consent regarding participation in the project and were allowed to drop out at any stage. In case of unexpected difficult experiences expressed towards the end of therapy, one extra therapy session could be provided to support them and let them be processed appropriately. Extra help could be offered through a cancer patients' counseling center, should any of the participants needed support in a long-term basis. Issues of confidentiality and anonymity had to be addressed; therefore, numbers were assigned to each participant, and identity was not disclosed in any written publication or oral presentation of the written thesis. No incentive, monetary or otherwise, was offered to the study participants.

2.3. DESIGN

2.3.1. RECRUITMENT

Details of the participants, setting, exclusion and inclusion criteria, and procedures are described in Article 2 for the feasibility and Article 3 for the RCT pilot. The project was advertised through "SONORA-Multidisciplinary Organization for Music Therapy & Research" as a campaign, via leaflets distributed through the hospital and in collaboration with its physicians in the Oncology, Surgery, and Pain Management departments. As the main researcher, I contacted women who expressed interest to the physician or myself directly or via phone and asked a few screening questions to see if they met the inclusion criteria. This was followed by an email with all written information and consent form to read in advance. Subsequently, those who were interested would book an appointment during which I explained the details of the program and procedures, and I informed of the voluntary nature of their participation. I answered any questions they may have had and provided clarifications. Furthermore, women completed the demographic questionnaire, and if they met the criteria and agreed to participate, signed the written consent form (Appendices C & D) and filled the baseline questionnaires.

2.3.2. PROCEDURE

For the feasibility study, women met with the therapist once a week for 6 weeks. Session format included pre-talk, relaxation, and induction, music listening and post-talk. The GIM method was adapted to be shorter in duration, with music with simple dynamics, and often with a singular focus (see Article 1). Before and after termination of the 6-week treatment women completed the psychometric questionnaires Hospital Anxiety and Depression Scale (HADS), and Functional Assessment of Cancer Therapy -General (FACT-G), and before and after each single session completed the two questions in Likert scales (fatigue, hope). Approximately 10 days after completion of treatment, as the main researcher, I interviewed each participant. The interviews lasted approximately 30-50 minutes and were recorded and transcribed. Allocation time until the completion of this first, feasibility part of the study was estimated to be 12 weeks.

Initials appointments, therapy sessions, and post-session interviews were meant to take place in a hospital room in the hospital, chosen carefully to meet the standards of a therapy environment. It was agreed with medical staff that bed and chair should be available in a room located in a quiet space, and disruptions from staff or external noise were to be avoided. However, since there was an uncertainty about the timely preparation of the hospital room, we considered the alternative of using the therapists' private offices for treatment.

The music options used in both parts of this investigation (feasibility study and RCT pilot) was the same and chosen by me as the main investigator based on the classic Bonny Method of GIM core programs namely *Nurturing*, *Mostly Bach*, *Peak Experience*, *Caring*, *Quite Music*, and *Positive Affect*. The selection of these specific programs was made (a) because they are considered amongst the least musically complex programs from the classic GIM core repertoire and (b) because all therapists taking part in the research were equally familiar with these same programs, so that all therapists would be selecting from the same options, as a fidelity strategy for treatment delivery. Programs were modified accordingly to serve the needs of this investigation (see Articles 1, 2) so that the most complex pieces of music were left out, and the music listening part would not exceed 20 minutes.

In order to maintain the therapeutic integrity, trained GIM therapists were instructed to choose the music driven by the individual needs that emerged in each session based on their experience, intuition, and therapeutic empathy. All therapists were instructed to play the music from their laptop playlists, using good quality speakers preferably located behind the head/body of the client, and adjusting the volume so that it would be comfortable enough for the client to hear and to be heard. Therapists also were instructed to adhere to pieces from these programs even for occasional use of short MI sessions, if needed, and not expand their repertoire otherwise. They also were instructed to offer the participants a choice of a sitting position instead of lying down, in case of physical discomfort due to illness, and to adjust the relaxation time and induction theme accordingly.

To ensure adherence to the protocol (but also as a question of the feasibility study) therapists were instructed to monitor their interventions in their logs regarding music choice, session duration, relaxation duration, focus of the session (if any), session frequency, and total number of sessions. Details on the intervention protocol and the monitored frequencies are provided in Article 2, whereas Article 1 provides with a full elaboration on theory and rationale for music choice.

2.3.3. SUMMARY OF ARTICLE 1

Article 1 provides more details on the theoretical background used for this study, criteria for music selection, and observations or findings that inform clinical practice in active treatment for cancer. It describes the set-up, the process, and the practical details that determine GIM work with this clinical population and gives suggestions for clinicians. It explains the theoretical underpinnings, based on the principles of psycho-oncology and supportive psychotherapy. It also elaborates on the theory used to formulate music and program choices. The article closes with a clinical vignette, highlighting spiritual aspects of the therapeutic process and their meaning and importance for patients with cancer.

2.4. DATA COLLECTION OF THE FEASIBILITY STUDY

In this section, I will explain some more procedural details, complementary to the information provided in Article 2. I will also provide a more detailed description of instruments used in the feasibility study.

Observational methods/event recordings: To address **Aim 1** and its subordinate questions about the feasibility aspects and procedures of this study, I collected demographic information (Appendix E) and recruitment logs (Appendix F), and therapists kept notes and logs on various aspects of the feasibility study (recruitment logs and session logs in column format, Appendices F & G). In addition, notes were used in the form of diary for the researcher that complemented the event recordings and included personal observations in order to collect information and evaluate feasibility questions: to identify key issues, problematic areas, limitations, and challenges, and generally matters that needed to be changed or developed further. These included practical difficulties and advantages of the study, according to points addressed in Table 2-1 above: (a) communication with health professionals in the hospital; (b) facilitation, (c) coordination, (d) acceptability from patients, (e) recruitment and consent/attrition rates, (f) elaboration of inclusion/exclusion criteria, (g) timing, (h) potential changes in the organizational setting to integrate the intervention, (i) inconvenience issues for the patients, (j) administration and assessment of psychometric tools in use, (k) intervention protocol, (l) selection of music for each session, (m) patients' needs that had not been identified earlier, and (n) overall strengths and drawbacks. Input from the patients' qualitative interviews (see below) provided additional highlights that informed further the feasibility part of the study. Information from such changes and patients' proposals informed modification of the next phase of the study and resolution of difficulties in implementing the therapeutic intervention so as to deliver a proper treatment protocol (Abbott, 2014; Bowen et al., 2009; In, 2017; Whitehead, Sully, & Campbell, 2014).

The demographic questionnaire collected information about age, education, professional status, marital status, and medical condition, including information on cancer diagnosis, type, date of diagnosis and stage of current treatment. In addition to this, I formulated a few initial screening questions to address relationship with music, history of psychiatric disease, or other current engagement with psychological therapies. As explained in previous section, the demographic questionnaire was completed during the initial interview with

the applicant, but the screening questions were used in the initial engagement with volunteers when checking with the physician to ensure compatibility before any agreement of participation in the study took place.

To address **Aim 2** and its sub-questions 2.1 and 2.2. about GIM's potential usefulness in various aspects of QoL, two standardized psychometric questionnaires were used at two time points, before the commencement of therapy (baseline) and after the series of treatment (post). The Hospital Anxiety Depression Scale (HADS) for anxiety and depression, and the Functional Assessment of Cancer Therapy-General (FACT-G) for QoL were chosen for practical reasons as they were rather short, both available in the hospital, recommended and used by the physicians, and available in Greek language.

The **Hospital Anxiety Depression Scale (HADS)** addressed sub-question 2.1. It is a practical tool for identifying and quantifying depression and anxiety, developed for use with physically ill, medical patients (Zigmont & Snaith, 1983). The role of the scale is mostly dimensional rather than categorical; HADS is a self-report rating scale of 14 items, and is designed to measure anxiety and depression, which commonly coexist, with 7 items for each subscale (HADS-D for depression and HADS-A for anxiety). It takes 2–5 minutes to complete and is generally well accepted by the patients (Herrmann, 1997; Stern, 2014). The HADS consists of brief statements that describe feelings such as the following: “I feel cheerful,” or “I get sudden feelings of panic.” Each item of the questionnaire has a 4-point Likert response scale. Scores are constructed by summation of the two subscales, whereby increasing scores indicate increasing burden (Erickson, 2005).

In a systematic review evaluating instruments for screening of emotional distress specifically in cancer, Vodermaier, Linden, and Sui (2009), found that amongst other short instruments available (fewer than 20 scales) HADS has been used across the cancer trajectory and with different types of cancer, different languages, and cultures. HADS provided with the most extensive validation, being tested against criterion standards. According to this review, when HADS' discriminant validity was compared against other scales and was found at least equivalent to those. It is available and validated in the Greek language (Michopoulos et al., 2008), has been used with non-psychiatric

patients, and its psychometric properties found similar with those of other languages; therefore, it is considered acceptable, reliable, and valid.

The **Functional Assessment of Cancer Therapy-General (FACT-G)** was used to address sub question 2.2 and measure alterations in general QoL. The instrument uses a five-point scale of agreement and is an established multidimensional measure that assesses the health-related QoL of patients; it is cancer-specific and has many dimensions in structure. It consists of four general subscales and evaluates patient's physical, social/family, emotional, and functional well-being. FACT-G has good reliability, validity, responsiveness to clinical change (Cella et al. 2003); it is self-administered, brief and easy to complete in a few minutes (27 questions) and applicable across a range of cultural settings. The four subscale scores range from zero to 28 for the physical, emotional, and functional subscales, and zero to 27 for the emotional subscale. Each subscale score is derived by adding together item responses and reversing the direction of the score when necessary. The initial score is multiplied by the total number of subscale items and divided by the number of answered items. The subscales are added together for a total score with a higher score showing a better QoL (Erickson, 2005).

On choosing FACT-G for this research, some considerations were made relevant to the group size to determine the optimal outcome measure. FACT-G has been considered against another popular instrument, the QLQ-C30 scale, for several reasons. FACT-G is most responsive to change over time within the global scale of the overall health-related QoL (HRQoL) and has greater statistical efficiency and power for change within a group or when comparing between two groups. Also, FACT-G requires one-third the sample of QLQ-C30 to detect changes in HRQoL, which is an important consideration for the small size group of this study. In the physical, emotional, and functional domains, FACT-G has good responsiveness, statistical efficiency, and power (King, Bell, Costa, Butow, & Oh, 2014).

FACT-G is reported to be less responsive on the social domain (King et al. 2014); however, this study is based mainly on psychological aspects addressed in individual therapy rather than explicitly social ones. Hence, another reason to choose FACT-G is because it addresses more clearly outcomes related to the interest of this study, such as relationships and support, and focuses less on purely physical side-effects (Luckett et al., 2011).

FACT-G is multi-nationally translated and therefore available and validated in the Greek language.

Two researcher-constructed **10-point Likert scales** addressed sub-question 2.3. (levels of fatigue) and sub-question 2.4. (levels of hope) respectively and were administered before and after every single session. Likert scale is an interval level of measurement; it is an approach that investigates a cluster of attitudes between two extremes and is very common format for measuring attitudes. Typically, a Likert scale is a fixed response scale of choices that provides the respondents with a series of statements, asking them how far they agree or disagree with these statements (Bryman, 2001; Coolican, 2014). Participants in the feasibility study were asked to complete a Likert Scale for fatigue (1 = not at all tired and 10 = extremely tired) and a Likert Scale for hope (1= hopeless and 10 = extremely hopeful) before and after each GIM session.

Semi-structured interviews: To address **Aim 3** and its sub-questions about participants' perceived experience, as well as part of the Aim 1 (1.3) questions on feasibility, as the main researcher I conducted semi-structured interviews (Appendix K) approximately 10 days after the end of each therapeutic series. A semi-structured interview was appropriate, for it focused on the meaning of specific phenomena to the participants. It was required to validate the quantitative measurements of this study or to clarify and illustrate the meaning of these findings, and it facilitated the exploratory work required before the experimental part of this investigation was carried out. This interview model is quite flexible and allows the interviewee to provide substantial information, as this form of interview is neither too open nor too rigid. A semi-structured interview is a moderate form in which a great amount of data can be elicited from the interviewee. Predetermined questions can be re-arranged depending on what seems appropriate, wording can be modified, and explanations can be given (Robson, 2002). A theme list was created to facilitate the process for the interviewer, and re-phrasing or re-ordering of questions, as well as omission/addition of questions could be performed to provide flexibility when more clarification or deeper understanding was needed. The questions were designed in a quite open way to encourage participants to offer descriptions of their experience; the underlying objective of the questions was to encourage participants to explain how they feel GIM affected them, and to describe how they were experiencing, feeling, or thinking about the processes involved. Participants' feedback also fed into questions around feasibility and

delivery for this treatment protocol and supplement Aim 1 and its sub-questions. In order to finalize the interview questions in terms of content and phrasing of sensitive questions, I received feedback on the interview draft from my supervisors and two clinical psychologists with expertise in cancer care, and I piloted the interview with the help of two colleagues for further adjustments.

As an interviewer, I familiarized myself in advance with the content of the interview so as to act as an active listener to help the participants feel at ease by being fully concentrated to their needs and expressions (Dempsey et al., 2016). The same open-ended questions were asked of each participant but in a flexible manner, and additional prompting, probing, follow-up, or clarifying questions were added to ensure rapport and to elicit further information. More notably, the interview guide consisted of an introduction to explain purpose of interview, confidentiality and permission to tape, some warm-up/introductory questions, structuring questions according to the main topics of the interview together with follow-up questions to give the opportunity to extend the interviewee's answers to previous questions, and closure questions. The questions addressed one main concept at a time with its follow-up questions, in a logical sequence from the more general to the more specific topics. Specific follow-up questions intended to get more information on the main interview topics were identified in advance in the interview guide. If the interviewee gave a rather generalized answer, a specific question could have been used to personalize the response, e.g. "Have you experienced this yourself?". Interpreting questions may also be useful in rephrasing an answer and putting it back to the interviewee as an attempt to clarify the answer (Kelly, 2010; Kvale, 1996/2006; Lacey & Luff, 2007; Robson, 2002).

The interview was intended to help the validation of the experience; interview questions focused on significant aspects of the participants' experience, their impressions, possible issues of practicality or burdens, and personal highlights of their personal experience. The interview guide consisted of questions in which participants were encouraged to (a) propose changes in the process, (b) point out important aspects of therapy and research process, (c) suggest points of improvement, and (d) evaluate the overall project design from the participant's view. Participants also could suggest additional topics or comments that would be useful to them. In this way, participants provided their personal input towards the second, experimental study.

2.4.1. SUMMARY OF ARTICLE 2

Article 2 gives a clear layout of the study design and its results and conclusions of a series of six Guided Imagery and Music sessions for women undergoing active treatment for gynecologic cancer, in a Greek hospital setting. Data from four women undergoing chemotherapy treatment were collected from measurements of HADS, FACT-G, and repeated-measures 10-point Likert scales for Hope and Fatigue, pre/post each single session, semi-structured interviews following therapy, researcher's, and therapists' notes. The results showed gains in hope and fatigue but no significant changes to self-reported anxiety and depression and QoL. In follow-up interviews, all four women reported that the music helped them cope with the disease and allowed them to deal with interpersonal and spiritual issues. All participants reported positive changes in their mood, fatigue, and levels of hope, although the changes were more apparent from their interviews than from the questionnaires. GIM can be feasible for this population; however, a number of considerations must be taken into account with regards to flexibility and management of sessions.

CHAPTER 3. TRANSITION TO THE RCT PILOT

3.1. SUMMARY OF THE FEASIBILITY STUDY DATA ANALYSIS PROCEDURES

Integration of data has been attempted in the phase of interpretation of the feasibility part, in which I examine ways that my databases may converge, diverge, or relate to each other (Bradt et al., 2013; Ferrets, Curry, & Creswell, 2013; Magee, 2016). Data from Aim 1 and Aim 3 from the feasibility study have been merged; data from Aim 1 have been converted into narratives (qualitized) and merged with interview themes related to the feasibility part of the study (Bradt et al., 2013; Onwuegbuzie, 2011). Qualitative data have been used to validate questions from standardized questionnaires and to show how qualitative findings may validate the results of those (Burns & Masko, 2016; Magee, 2016; Meadows & Whimpenny, 2016).

Practical implications of the results were considered, and the importance of the feasibility study has been summarized. The feasibility part informed recruitment, retention, assessment procedures, and implementation of GIM as a novel intervention for this clinical population. Limitations of the current research have been identified, along with suggestions for how the second part of this investigation can build upon the findings of the feasibility. Study components that are deemed infeasible or unsatisfactory have been modified in the subsequent study or removed altogether (Leon, Davis, & Kraemer, 2011).

3.1.1. ANALYSIS OF INTERVIEWS

In this section, I will explain in more detail how analysis of the interviews has been performed. As main researcher, I transcribed semi-structured interviews verbatim and later, an assistant compared transcripts with the recordings to identify any omissions and make corrections. I analyzed and evaluated transcripts using thematic analysis in order to gain information about the feasibility questions, and analysis of the patients' experiences. The interview narratives were treated with respect to what they can show about contextual features of the experience, thus, to give a description of what a woman

experienced during the treatment period and provide some directions for further planning and practice.

Analysis of interviews involved identification of pertinent themes. Through repeated reading of the transcripts, themes and sub-themes emerged and were grouped together into clusters of concepts and headings were identified (Braun & Clarke, 2006; McFerran & Grocke, 2007; Robson, 2002; Smith, 1995) with the aim to address the study objectives, research questions, and other information that may emerge. This thematic analysis refers to identifying and reporting patterns within the interviews and it was chosen for its flexibility and theoretical freedom (Braun & Clarke, 2006). A “theme” captures something important about the data in relation to the research; it can offer the opportunity to go beyond counting explicit words and phrases and capture a whole patterned response or meaning within the data set. The analysis was based on a rich description across the entire data set, appropriate for such an under-researched area. Both inductive and deductive coding were used. Coding was guided by quite specific research questions; yet, new information could evolve through the coding process. An inductive approach was also followed, in which coding was performed without trying to fit into a pre-existing coding frame based on the researcher’s preconceptions (Braun & Clarke, 2006).

The process of analysis started with reading and re-reading the transcripts, so that the first observations of potentially interesting features in the data and patterns of meaning could emerge without being organized into concrete themes. I underlined those patterns and points of interest in a systematic fashion, and in the next phase I provided initial codes for them, trying to collate data relevant to each code. I generated preliminary titles for the emerging themes, as they came out of the gathered-together data. I reviewed the data again to decide which were the main themes that could create the “map” of my analysis and also define the specifics of each theme and relevant information that could qualify as sub-themes. Finally, I provided definitions and headings/names for each one of them for my main themes and their subthemes (Braun & Clarke, 2006, Robson, 2002; Ryan & Bernard, 2000). Table 3-1 is an example of the thematic analysis procedure followed in this study.

Data extract	Coded for	Theme	Subtheme (s)
Length of session was OK for me... This was just what I needed, I couldn't take much more in. But there could be more sessions, I felt I needed some more time to let go	Length of session good More sessions needed	Design	Length of session Duration of therapy

Table 3-1. Example of the process followed during thematic analysis

The results of the full analysis are illustrated in Article 2.

3.2. SUGGESTED CHANGES DRAWN FROM THE FEASIBILITY RESULTS

The findings from the feasibility study showed that the aspects of mood, hope, and fatigue were found to be important for the participants, who in their interviews did not bring forward any other issues or needs that could potentially be addressed as new variables in the second part of the investigation. The feasibility study also revealed that changes in outcomes could not be registered through the selected measurement tools. Therefore, changes of the questionnaires needed to be considered, given that HADS and FACT-G were found not suitable. HADS was replaced by a similar instrument; since all women in the feasibility study described positive mood changes in their interviews, a measurement on mood seemed more appropriate as a replacement for HADS. Moreover, the participants valued the experience as relaxing and hopeful, affirming the significance of the variables of fatigue and hope respectively (see Article 2). Thus, instead of a general QoL instrument, three questionnaires focusing on the specific variables of the study (mood,

fatigue, hope) were used, since the feasibility results showed some trends towards this direction. This decision also was based on the fact that there are no questionnaires similar to FACT-G available in Greek to be used as an alternative measurement of overall quality of life.

The feasibility study shed light on practical issues that needed further consideration and adjustment to facilitate future research studies and clinical practice. It was clear that the recruitment process was more successful when managed by oncologists, rather than by the main researcher or by leaflets and posters. The feasibility also pointed to all organizational difficulties of a public hospital that prevented proper accommodation for the GIM treatment, issues of privacy, and limited physicians' availability, suggesting that a future study could be more manageable in a private hospital, or any hospital with better organizational management and more predictable workload.

The intervention was feasible for women during their course of chemotherapy, although clinicians should consider constant adaptation and flexibility with regards to schedule or therapeutic intervention. However, planning a research study under these terms may raise a lot of practical inconveniences; therefore, piloting the trial is essential before any large-scale research takes effect.

All these observations and suggestions drawn from a single-arm, descriptive feasibility study, have been brought forward to inspire the formulation of the design of a small experimental study, an RCT pilot. For the RCT pilot, the recruitment process will be directed by the physician. More notably, the treating oncologist will consult the daily calendar of those having appointments for chemotherapy sessions to identify women who meet the study inclusion criteria. The physician will only exclude women whose medical condition she considers to be too frail. Then, the physician or her assistant (a psychologist) will meet these women (in the consultancy room or in their chemotherapy chamber) and talk to them about the research before I—as the main investigator—introduce myself to them (more details about recruitment can be found in Article 3).

For the RCT pilot, appointments took place in the therapists' offices located closer to the participants' residence. Each therapy session was scheduled by telephone or email with the therapist, and research questionnaires were replaced. Moreover, in this second study women with breast cancer also were included. Inviting a target population with other types of cancer is hoped to optimize the recruitment rates, since there are more women with breast

cancer in the hospital. Finally, although in the feasibility study there were no exclusion criteria based on residential areas of patients, there was, however, a preference for women who lived in the Athens area for practical reasons. This observation was followed by some concerns about the ethicality and selection bias of excluding those who meet the criteria and are willing to participate, judged by distance only. Therefore, women living in distant areas were invited into the RCT pilot study. Figure 3-1 below depicts the design and process of the two parts of this investigation.

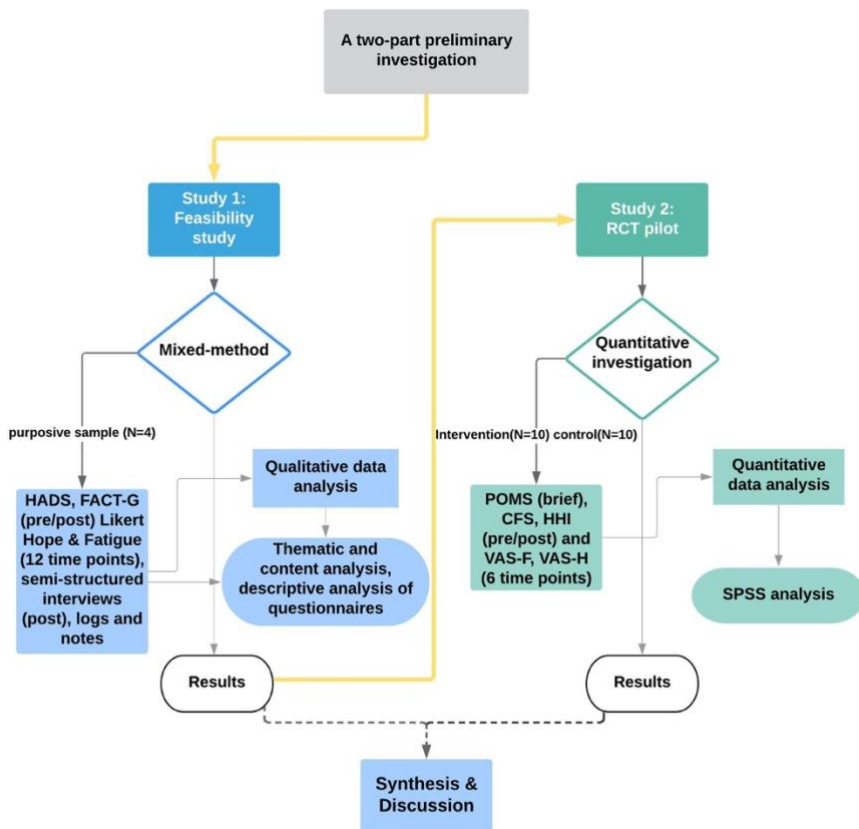


Figure 3-1. Design and process of the two studies of this investigation

3.3. REVISION OF THE RESEARCH QUESTIONS AND QUESTIONNAIRES

The main questions of the research have been revised. In this second part, I seek to evaluate whether six sessions of short GIM can 1) improve mood, 2) reduce levels of fatigue, and 3) increase levels of hope during active treatment for breast/GC compared to standard care. To assess these questions, I carefully thought about my options in new questionnaires as replacement or complement of the previous ones. In this section, I will make a thorough description of the new instruments, with rationale on choice and expected benefits. This information is complementary to the questionnaire description provided in Article 3.

To address Question 1 whether GIM is helpful at improving mood during the period of active treatment for breast/GC compared to standard care a **Brief version of the Profile of Mood States (POMS)** modified in Greek language has been used (Appendix L). POMS (McNair, Lorr, & Droppleman, 1971) is frequently used to assess a range of feeling states. Each one of its adjectives represents a mood/feeling descriptor. Respondents indicate the degree they have experienced each one of the moods that describes the frequency of this feeling over the past week, in a 5-point scale from 0 (not at all) to 4 (a lot).

The original version of POMS consists of 65 items has been considered difficult and time-consuming when used with cancer patients who have limited stamina. Therefore, shorter versions have been available to be more manageable and easier to complete in a few minutes (Cella et al., 1987; Guadagnoli & Mor, 1989; Lesiuk, 2015). For the purposes of this research, a modified POMS-Brief version has been used, modified and adapted in the Greek language (Roussi, 2001, 2012) consisting of 30 items. The items are divided in six domains namely tension, depression, vigor, anger, confusion, and fatigue. The questionnaire is a sum of these 6 sub-domains, with a total score from 0 to 120, and lower scoring indicating better mood states.

The adapted Greek version of POMS has been found to have satisfactory construct validity and psychometric properties (Roussi, 2001, 2012; Roussi, Krikeli, Chatzidimitriou, & Koutri, 2007) with good internal validity. POMS brief in this study had high internal consistency index for the pre (Chronbach's $\alpha = 0,88$) and the post (Cronbach's $\alpha = 0,87$) intervention measurements.

POMS brief has been used as a replace of the HADS questionnaire previously used in the feasibility. POMS is frequently used for assessing mood states associated with psychotherapeutic interventions in clinical evaluation or research with cancer patients during chemotherapy treatment as opposed to HADS, which is mainly used to assess clinical levels of anxiety and depression in inpatient and outpatient medical units (Erickson, 2005). Moreover, it sometimes has been considered too lengthy (Mitchell, Meader & Symonds, 2010). Two measurements were taken with POMS Brief, baseline (pre) and after the termination of therapy (post).

To address Question 2 about GIM's possible usefulness in reducing fatigue levels, The **Cancer Fatigue Scale (CFS)** has been chosen (Appendix M). CFS is a brief, self-rating scale, designed to reflect the specific nature of fatigue experienced by people with cancer. Another advantage of the scale is that it is simple and quick to complete even for advanced cancer patients and has good validity and reliability (Okuyama et al., 2000). CFS is a multi-dimensional instrument, composed of three fatigue factors in 15 questions, addressing physical (7 items), cognitive (3 items), and affective (4 items) dimensions of fatigue. Each of the 15 items is assessed on a 5-point Likert scale. The three different factors can be calculated separately, but the CFS also gives a total score by adding all factors together. Higher scores correspond to higher fatigue levels.

The scale has been translated and validated in the Greek language by Charalambous, Kaite, Constantinou, and Kouta (2016) in a study recruiting patients with advanced prostate cancer in active chemotherapy. It was translated from the English version through a 5-step approach according to Beaton's guidelines (Beaton, Bombardier, Guillemin & Ferraz, 2000). Overall, the scale appeared to be valid and reliable for measuring fatigue for the population in study; the internal consistency of the total scale of the instrument was found to be high (Cronbach's $\alpha = 0.9$), the stability was found good ($r = 0.79$, $p < 0.001$), and the criterion validity was verified. In this study, CFS had high internal consistency index for the pre (Cronbach's $\alpha = 0.85$) and the post (Cronbach's $\alpha = 0.89$) intervention measurements. Two measurements were taken with CFS, baseline (pre) and after the termination of therapy (post).

Question 3 about the potential of GIM to increase levels of hope, have been addressed with the **Herth Hope Index (HHI)** developed by Herth (1992), assessing levels of hope (Appendix N). HHI is a shorter version of the Herth

Hope Scale developed by the same author. Initially, it was based on the theories of Lazarus and Folkman about stress and coping skills (1984), combined with Stotland's (1969) theory about hope, where hope is considered as a psychodynamic process related to other factors such as motivation or achievement, and is multi-dimensional concept including thoughts, emotions, actions, and relationships. Later, Herth modified the scale and incorporated the theoretical model of hope by Dufault and Martocchio (1985) which is the one most often used with cancer patients (Tsaroucha, 2014). According to this model, hope is a multi-factorial individual process that changes over time, and its apprehension is highly dependent on the unique state of the person who is suffering from a threatening condition, like cancer.

The instrument is short, clear, and consists of 12 questions in a Likert Scale from 1 (*strongly disagree*) to 4 (*strongly agree*). The questions are categorized in 3 sub-scales: (a) interconnectedness, (b) positiveness and expectancy, and (c) temporality and spirituality. Scoring consists of summing the points of the subscales. Scores on the total scale range from 12 to 48 with higher scores indicating higher levels of hope.

The internal consistency of the original questionnaire is high (Cronbach's $\alpha = 0.91$ – 0.97 ; Herth, 1992). HHI has not been officially translated and validated in Greek. The current version has been translated by Tsaroucha (2014), following the back-to-back translation process by independent translators. The psychometric properties were tested in two pilot studies, one with 110 patients in a hematopoietic stem cell transplantation unit and the second with 60 patients with chronic or terminal illnesses. Both were found to have good results (Cronbach's $\alpha = 0.87$ and 0.83 , respectively). The translated questionnaire has been used with permission from Tsaroucha (2014), and it subsequently went through a committee of experts to get a consensus in terms of semantic, idiomatic, and conceptual equivalence. The committee consisted of two psychologists, one translator, and two language professionals. In this study, HHI had high internal consistency index for the pre (Cronbach's $\alpha = 0.91$) and the post (Cronbach's $\alpha = 0.91$) intervention measurement. Two measurements have been taken with HHI, baseline (pre) and after the termination of therapy (post).

In order to gather further convergent validity evidence, two researcher-constructed **Visual Analogue Scales (VAS)** have been used (Appendix O) to address Questions 2 (fatigue) and 3 (hope) complementary to the multi-item

questionnaires. A VAS is a single subjective measurement often used for the assessment of fatigue and hope, in various settings including cancer providing with an extra indication of the effectiveness of therapy (Aaronson et al., Erickson, 2005; Lee, Hicks & Nino-Murcia, 1990; Nikolaichuk & Bruera, 2004; Ream et al., 2006; Richardson, Ream & Wilson-Barnet, 1998, Strebkova, Petkova & Minev, 2017).

VAS is easy to administer, a fact that makes it attractive to use for a group with physical or psychological limitations; therefore, it can be used in every session. It can give frequent measurements on immediate, short-term effects, and indicates how the sessions work between pre- and posttesting. Operationally, a VAS is usually based on a horizontal line, 100 mm in length, anchored by word descriptors at each end, and the client makes a vertical mark on place the line that represents the perception of the current state. Respondents completed VAS of Fatigue (VAS-F; 0 = *very tired* and 100 = *extremely refreshed*) and VAS of Hope (VAS-H; 0 = *no hope* and 100 = *extremely hopeful*) measurements six times, after each GIM session. For the control group, a reminder was sent to complete the scales once a week.

Although VAS and Likert scales show comparable responsiveness, VAS has been chosen in replacement of 10-point Likert Scale used for the feasibility, for it implies an underlying, continuous linear relationship, whereas Likert Scale is more of a hierarchical order between categories, and thus, does not inherently imply linearity. In contrast to discrete Likert-type scales, VAS places fewer restrictions on the range of choices, thus being more responsive, allowing for greater precision and containing a larger amount of information (Guyatt, Townsend, Berman & Keller, 1987; Hasson & Arnetz, 2005; Kim, 2017; Klimek et al., 2017). It could also be argued that a VAS is trying to produce interval/ratio data out of subjective rates and estimations that are at best ordinal (Visual Analogue Scale, 2019). There are controversies in the literature regarding the character of the VAS as ordinal, interval, or ratio scale, that the level of measurement would be defined by the kind of variable and the parameters to be measured and thus, would determine the type of statistical analysis. For example, based mainly on pain research, some authors do not recommend the use of parametric statistics for VAS measurements because they attribute to it only ordinal qualities (Kersten, Küçükdeveci, & Tennant, 2012); however, Price, Staud, and Robinson (2012) oppose this view. They base their conclusions on known psychometric features of VAS that support interval and ratio scale properties,

which can predict more accurately separate judgments of ratios on the intensity of the phenomenon in question. Moreover, measures that are represented by a percentile are usually classified as ratio scales and VAS can be used as such in similar occasions (Kim, 2017). For my study, I consider that VAS can provide not only ordinal, but also interval and even ratio measurements that start from a real, distinct zero point to reflect accurate ratios or proportions of the variables in question over a stimulus-response curve (Coolican, 2014, p. 339; Price, McGrath, Rafii, & Buckingham, 1987; Price et al., 2012).

3.3.1. SUMMARY OF ARTICLE 3

This article describes the design and methodology of the RCT pilot for women with gynecologic or breast cancer undergoing treatment. Participants were randomized into an intervention and a control group consisting of 10 participants each; the intervention group received a series of six individual GIM sessions and the control group received a placebo of two verbal supportive counseling sessions at the beginning of Week 1 and at Week 6. All women completed the Profile of Mood States (POMS-Brief), Cancer Fatigue Scale (CFS), and Herth Hope Index (HHI) questionnaires before Week 1 (baseline) and after Week 6 or after last GIM session. All participants completed two VAS (for hope and fatigue) six times, each after GIM session for the intervention group and for six consecutive weeks for the control group. Results indicated a significant difference in increased hope levels as shown VAS-Hope results, and decreased fatigue levels for the intervention group as also measured by VAS-Fatigue; although there was no statistically significant change for the GIM group as measured by either HHI, CFS, or POMS, the medium effect size for the experimental group while the control group remained unchanged indicates that short GIM sessions concurrent with chemotherapy may have therapeutic benefit in increasing hope levels, decreasing fatigue, and improving mood for women with breast or gynecological cancer and supports the need for future research with a larger sample from this population.

CHAPTER 4. INTEGRATION AND DISCUSSION

In this investigation, I sought to explore the feasibility of shortened GIM individual sessions in an outpatient oncology unit and its potential impact on QoL, and specifically on mood, fatigue, and levels of hope for women over the course of a curative or advanced cancer treatment for breast or gynecologic cancer. In addition, I wanted to explore the feasibility of GIM as psychological therapy during a course of active chemotherapy treatment, especially in a Greek hospital setting where it has not been attempted before.

In the context of this investigation, all psychological variables chosen are of clinical relevance for women with gynecologic and breast cancer receiving treatment. According to the literature review, this is the first study investigating the potential of GIM as a one-to-one supportive intervention for women in gynecologic oncology receiving active treatment in a more systematic way. Findings of the two parts of the study have been presented and discussed in Articles 2 and 3. In this chapter I will summarize the findings of both study parts, reflect on them in terms of practical considerations and the strengths, and limitations of the methodology and study design, and present conclusions and implication for future practice and research.

4.1. SUMMARY OF THE TWO STUDIES

The feasibility study was based on a purposive sample of four women with gynecologic cancer who consented to participate in six approximately weekly GIM sessions. The women filled out the HADS and FACT-G questionnaires before (baseline) after the completion of the intervention and filled out two 10-point Likert scales for Fatigue and Hope before and after each session. At the end of the intervention they were invited to an interview to evaluate and validate their experience as they perceived it. All women described GIM as a positive experience with a significant effect on their mood, fatigue, and hope levels; they all found space to explore relationships with self and others within the GIM process, as well as spiritual issues. The questionnaires HADS and FACT-G, however, did not

confirm these changes in this small sample, even though the Likert scales showed a decrease in fatigue levels after the intervention for three women and positive changes at hope levels for two women.

As a consequence of the findings from the feasibility study, the psychometric instruments in the pilot study were revised and replaced with POMS (brief) from mood, and two more specific questionnaires for fatigue (CFS) and hope (HHI) at the same times as before (baseline and after completion of intervention), complemented with the respective VAS scales for hope and fatigue measured at six time points. The pilot was an experimental study (RCT) with an intervention group ($n = 10$) receiving six weekly GIM sessions and a control group ($n = 10$) receiving one verbal counseling session at first week and another session after six weeks, while completing the same questionnaires. The results showed a significant positive change in hope and fatigue levels as shown by the VAS, but the standardized instruments HHI, CFS, and POMS did not confirm significant changes at hope, fatigue, and mood for the intervention group, despite medium effect sizes.

All participants engaged positively and were able to cope with the length of session and strength of music chosen and adapted especially for this client group. There were only a few exceptions where adaptations had to be made occasionally to facilitate physical limitations, for example, patients remained in a sitting position instead of lying down. However, rarely were there sessions consistent with the planned weekly appointments, and many changes and much rescheduling had to be made, extending the overall intervention period from 6 to 18 weeks. Many revisions had to be made to the recruitment protocol with physicians being more involved in the process, whereas we had to deal with practical difficulties with regards to timing and location/proper therapeutic space to conduct the sessions, which were eventually resolved by offering the majority of sessions outside the hospital. Eventually, this change had a positive outcome for the study as most of the participants were more comfortable receiving a supportive therapy outside the hospital setting due to negative associations with the hospital. A few more aspects regarding the feasibility and piloting of these two preliminary studies will be discussed in detail in this chapter.

4.1.1. REFLECTIONS ON RESEARCH QUESTIONS

When I was originally thinking upon the research questions, I was mainly driven by what the literature seemed to suggest as predominant factors of health-related quality of life and well-being of these patients. I had decided to focus primarily on women with gynecologic cancers, since there is less research for the psychological needs of this population and even less for the Greek population, thus hoping that participants would provide me with a new insight about their needs and help me formulate new questions for the second study arm based on these characteristics. Inspired by previous studies of MI in gynecological cancer (Hertrampf, 2017; Wårja, 2018), I speculated that women would touch more intimate emotions and existential states generated not only by their cancer but also by the specific types of cancer that affects their feminine qualities, including sexuality and motherhood. Nevertheless, the participants in the first arm of the study, did not disclose towards this more intimate direction and reported that all study variables were highly relevant to them without adding new ones. Shame, inferiority, or worthlessness previously reported by Wårja (2018) were not in their agenda. This might be explained by the fact that the study recruited patients during active cancer treatment, not in the rehabilitation phase. Most of them were in a survival mode (Faulkner & Maguire, 1994) in the middle of a struggle that did not give them the opportunity to touch upon sensitive areas and reflect on the consequences of the disease on their body and soul. Another possible explanation is culturally based, and the fact that people in Greece do not easily open up to speak openly about the “taboo” disease (General Secretary of Public Health, 2015). Though this topic was not researched with specific instruments in this study, some evidence from the interviews as well as observations and discussions with physicians, patients, and Greek psychologists with expertise in cancer care along this research project, corroborated these views.

The above reflections do not mean that the original set of research questions was not relevant. Indeed, participants valued the elements in question as worth exploring and agreed that they were prominent in their encounter with the disease. They valued the variables not only in relation with cancer, but also as important in their lives in a general context. These testaments were in line with the GIM and music therapy literature indicating the importance of the specific study elements, such as hope,

development of coping strategies, and relaxation (Bonde, 2005; Bro et al., 2018; Dimiceli-Mitran, 2015; Gimeno, 2015; Hertrampf, 2017; McDougal-Miller, 2016; Meadows, 2015). Under the circumstances, both study parts were formulated around similar research questions, slightly modified, and dependent on the psychometric tools available.

4.1.2. REFLECTIONS ON INSTRUMENT SELECTION

Selection of instruments was a rather challenging task. Major difficulties occurred in making well-aimed and appropriate choices, as I found out that there is a limited variety of standardized tools translated and validated in the Greek language.

It was my initial intention to explore overall QoL with an instrument that would be all-inclusive of various QoL parameters. FACT-G was carefully chosen amongst similar instruments for its good properties as it is a tool widely used during active cancer treatment; however, it did not detect any differences in the feasibility study, excluding its use at the second arm. Perhaps it is because the study did not have a sufficient number of participants (*N*), therefore it was underpowered, as suggested by the effect sizes. Maybe it is not possible to get a sense of an overall QoL changes when you are in the middle of cancer treatment, trying to survive and overcome the disease. Consequently, the research question around the overall QoL was withdrawn for the RCT pilot.

HADS was another tool that did not work satisfactorily for the initial feasibility sample. HADS was recommended by some physicians and was a convenient choice, because it was available in the unit. HADS, however, is diagnosis-oriented and could not detect changes to participants without clinical signs of anxiety or depression. I realized that for the second study arm I had to seek for a more sensitive instrument that could respond to mood changes in a more flexible way. POMS seemed to provide with the qualities I wanted, and I opted for it. The original version of POMS was not available as a brief version in Greek and the long version of 67 questions was not appropriate for my clients with such limited stamina. Luckily enough, I discovered another brief version of POMS, modified in the Greek language by Roussi (2001, 2012), which had been previously used in cancer research with success. POMS-Brief did not manage to identify statistically significant differences in such a small sample,

nevertheless, the medium effect size shows that we can still capture some clinical relevance from the effects of the intervention (Gold, 2004).

Likert scales and VAS for hope and fatigue provided some significant results, as they were sensitive enough to capture immediate effects based on multiple measures, so that the research was not hindered by the small *N* of the subjects. Furthermore, the fact that in the feasibility study the Likert scales were administered before and after each single session, helped in identifying the positive differences for the women and the immediate effect on the same session as a result of intervention. I decided to keep these scales for both study parts, because they were very direct and focused on specific outcomes. As they were repeated measures instruments, they produced a lot of data at every given moment across the intervention with six different time points, as opposed to the standardized instruments which had only two time points at the beginning and ending of the intervention.

Based on the results of the feasibility study with positive changes in hope and fatigue, I decided to complement these two variables with two standardized instruments. There were a few good choices for fatigue scales; however, I could not obtain license to use them, or the authors who had validated them in Greek did not respond to my requests. The CFS questionnaire was amongst my chosen ones, but unfortunately, like POMS, it was not sensitive enough to detect statistically significant changes, although it did reveal medium effect sizes for the intervention group. Similar findings apply to the HHI; nevertheless, this was not an officially validated measure; I used a Greek version previously used by Tsaroucha (2014) with permission from the author (Herth, 1992), which underwent further semantic analysis by a group of experts whom I invited. Based on the good qualities and responsiveness of HHI as well as on the need for a validated and reliable instrument for measuring hope in Greek, I would strongly encourage Greek researchers to work towards an official validated version. Figure 4-1 below illustrates the overall instrument selection for both study parts. It describes how research questions have been addressed in each study part and highlights the changes that have occurred between the feasibility and the RCT pilot study.

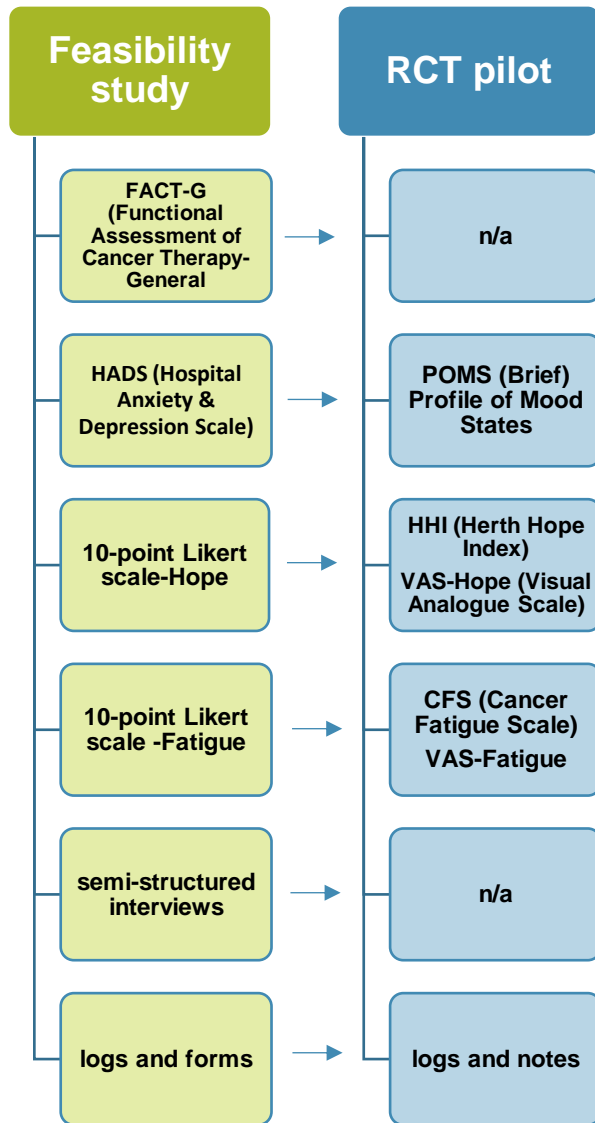


Figure 4-1. Instruments used in the two parts of the study

Although I used semi-structured interviews only for the first arm of the study, elaborative, qualitative information from more participants would have added value to the project. Data collection from big samples was not feasible in this study due to time restrictions, but future research could focus more on the perceived experience of the patients, as they may provide an additional perspective, useful in clinical research and design.

They may capture dimensions of the therapeutic essence that cannot be adequately described or quantified via standardized measures.

In both studies, we used logs and notes as points of reference throughout the process. Logs were useful in providing information about frequencies. However, many of the observations on the feasibility and pilot aspects of this study are based on my lived experience as main investigator and coordinator of the research protocol.

4.1.3. REFLECTIONS ON PRACTICAL AND CULTURAL ASPECTS

Recruitment and compliance for this study was much more difficult than anticipated and many changes in the recruitment process were made across the two study parts. In the recruitment process, I made some observations that seem to emerge an unexpected dynamic that could have its origins in more culturally related issues. Although this is not the focus of this study, I would like to share some short reflections on culture based on these observations, especially since this was the first time that music therapy and the GIM method were applied in a Greek hospital context.

In contrast to the preview study on gynecologic cancer by Wärja (2018) based on self-selected patients in Sweden, participants of this study agreed to participate mainly after encouragement by the medical oncologists. Patients in this investigation did not respond either to leaflets or posters, nor were they convinced after my introducing the project to them verbally. Although no systematic evidence was collected with regards to the reasons of refusal to participate, from verbal feedback received from the physician and her assistant, the most popular reasons were (a) "I don't have time for these things," (b) "I am not interested in psychological therapies", and (c) "I already feel supported by my family." This may be seen as a result of cultural diversity or socioeconomical level; Greek patients are not familiar with psychological interventions within cancer care. Since most hospitals in Greece do not operate within an integrative medicine model—and consequently do not embrace a psycho-oncological perspective—patients are not familiar with such approaches and this fact should be acknowledged by clinicians and researchers. Greek patients do not easily open up to speak about the "taboo" disease in a comfortable manner (General Secretary of Public Health, 2015), and

they remain skeptical in trying something “new” unless introduced by the treating oncologist, as a valid authority figure. These findings are derived from the interviews; some observations and discussions with medical staff, patients, and Greek psychologists with expertise in cancer care along this research project; as well as testimonies from my previous clinical experience which corroborate these views. Furthermore, patients’ compliance must be taken into account. Volunteers in this study often raised issues of preferences with regards to groups assignment, resulting in a substantial number of them refusing to participate in a randomization process that would not allocate them to their preferred condition (Preference Collaborative review Group, 2008). There also was an additional issue of genuine motivation. Based on my personal observations and feedback from the therapists in this study, even for a couple of the volunteers who signed consent, one could get the impression that they were participating as a “favour” or because did not want to disappoint the physician, although participation might feel like a burden to them. These findings are important, as they specifically indicate the significance of good communication and building alliance and trust as part of the recruitment process with respect to patients’ attitudes and expectations (Chharte et al, 2018).

One more consideration was raised about the location of therapy. I was highly concerned that most Greek hospitals do not have appropriate facilities for complementary therapies provision, except for some private hospitals. Lack of room was also the case in the first study, but in the second study, we were lucky enough to be offered a small waiting-room with a comfortable sofa in the private affiliated clinic in which to provide therapy to those women living in distant areas. As an alternative option, I had selected GIM therapists providing services in different parts of the city so that the participants were assigned to the therapist living closer to them. Interestingly, most participants admitted that having therapy outside the hospital was a more attractive option as the “hospital” was highly associated with the disease. We also found it necessary to schedule home visits for some patients whose physical condition was rather frail. The findings indicate that a GIM therapist must be prepared to provide alternative options and be flexible when working with such populations. Such flexibility can be acknowledged as an indicator of sensitivity and respect for their needs. Thus, the actual location of where the treatment is offered might influence greatly the physical and mental energy and the

patient's ability and motivation to engage in the intervention and develop trust in the process.

Table 4-1 provides a detailed description of the outcomes of the feasibility and pilot aspects of the study. The table has been formulated according to Abbott's list (Chapter 2) to present the findings of this study based on notes and observations on practical issues, recruitment, randomization and blinding processes, treatment fidelity, attrition rates, retention and adherence, data completeness, as well as problems and challenges at all stages of the study.

Feasibility outcomes	RCT pilot outcomes
<ul style="list-style-type: none"> • Volunteers did not self-refer based on written material (posters, flyers) • Access to participants only after physician's involvement • Physicians collaborate well but not always available • Distance, mentality, or health condition could be barriers to participation • Assessment procedures were adjusted/ outcome measures replaced • Adequate time/resources required to conduct assessments • Problems with willingness of the participants to be randomized to the proposed treatment groups • Intervention could be deliverable in a private clinical setting • But there are barriers to clinical delivery of the intervention in a public health 	<ul style="list-style-type: none"> • Recruitment completed in 14 months (instead of 8) with an average enrollment rate of 1-2 participants per month • 43 volunteers screened for eligibility with a consent rate 47% • Randomization processes did not work smoothly because of volunteers' preferences to the assigned groups • Degree of effective blinding was uncertain due to small number of staff • Good capacity/resources to conduct all trial processes • Good access to equipment and space • Satisfactory treatment fidelity with no further changes to the clinical intervention protocol • Sessions timing/frequency can be problematic due to participants' physical restrictions. Nevertheless, all reported as benefited from the intervention, regardless of the

<p>care system due to practical issues</p> <ul style="list-style-type: none"> • Clinicians' adhered to protocols and made appropriate adjustments (e.g. increase session time) • Good acceptability to patients of the treatment and adherence to treatment • Appropriateness of target group for intervention was good but a research protocol needs be flexible • Multi-sitting of clinical work was essential to facilitate access of participants to sessions. • However, the protocol cannot be easily supported in a multi-site research environment due to practical management and financial restrictions. 	<p>intensity and inconsistency in session scheduling</p> <ul style="list-style-type: none"> • Assessment processes were timely and complete • Satisfactory participant retention amongst the allocation groups, with a good distribution and equal size group numbers • Attrition rates were satisfactory at 15% • Data completeness was satisfactory and treatment effects were consistent with expectations/previous literature • Not so many challenges faced by site or personnel, but researcher had to be quite persistent to achieve communication
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Table 4-1. Studies Outcomes

As seen in the table, despite all the difficulties, we managed to recruit the desired number of participants, although we had to extend the recruitment period and complete the program to 14 months instead of the 8 months initially scheduled. Moreover, the results on the themes in question are consistent with previous literature, but the measurements need further revision through further pilot testing for more sensitivity and accuracy. One difficult issue in conducting large scale research, is duration of treatment which cannot be equally distributed and consistent due to unstable conditions. It is reasonable and expected that clinicians choosing to work with cancer patients in treatment are prepared to be flexible upon scheduling and adjusting of the sessions. However, this reality cannot easily be overlooked when scheduling a big research project with strict timelines or deadlines. Except for this, most of the other problems identified are surmountable, and can be fixed with further modifications, provided that careful consideration will be given to the aforementioned points mentioned in Table 4-1.

4.1.4. REFLECTIONS ON THE INTERVENTION AND THEORETICAL MODEL

The proposed layout and structure of the GIM sessions of shorter duration and simpler music often with a given focus worked well for all participants in the two study parts. The good correspondence and feedback of the participants indicated that patients in chemotherapy can benefit from GIM, consistent with the findings of Bonde (2005). In the feasibility study, the planned session time was 50 min, but it turned out that the length of session could be extended, to make it a 60-min session. Participants in the feasibility study expressed the wish to have more than six sessions as they felt they needed more time to “open up”. Although increasing number of sessions would be a recommendation consistent with previous literature (Burns, 2001; McKinney & Grocke, 2016), I felt that a proposal of 10 or more sessions in such a fragile population could work as a deterrent for new volunteers, limiting the options for commitment to the project. Hertrampf (2017) reported similar observations with most participants admitting that although they would like more sessions, if these sessions were presupposed, most likely they would have refused participation. In fact, even if they so liked it, none of the four participants of the feasibility study made use of the extra sessions voluntarily offered by the therapists at the end of their series, confirming the above. Additionally, having included advanced cancer patients in this study, increasing sessions number would be a limitation and contraindication for them as they could only sustain even fewer sessions (Warth et al., 2015).

On the contrary, length of session and music was substantial. Music selected for this study was manageable and women could tolerate its properties very well; they did not get tired or disturbed by its qualities and length, and most of them stated there was no need for more music. The qualities of the supportive, small-medium music containers helped them stay “tuned” around the initial positive focus of their music journey, allowing for a deeper, resourceful connection with that. These observations confirm the appropriateness of the intervention design with a session time up to 60 min and up to 20 min of music, based on simplified selections of GIM programs. They also justify the criteria used for choosing music, which was intended to provide a supportive framework within which participants could connect with positive resources, revive pleasant memories, associate with spiritual qualities and realms, and feel physically or mentally relaxed. The use of a specific, usually positive, imagery focus suggested in the induction worked as a useful adjunct, as it

helped women to stay around the same experience, avoiding exhaustion of resources as a result of fluctuation amongst many different feeling states or difficult images. These observations are in line with previous clinicians and researchers proposing similar adaptations to the method, to accommodate patients with less energy and limited resources (Clements-Cortés, 2016; Justice & Kasayka, 1999; McDougal-Miller, 2016).

Music was chosen within the principles of the supportive psychotherapy model appropriate for work in psycho-oncology, especially during the period of receiving chemotherapy (Mukherjee et al., 2017) when the level of capacity and energy varies widely amongst participants. This is of high clinical significance as it resonates with the theoretical framework of psycho-oncology and reflects the therapeutic stance generally used in the study. It acknowledges the properties of the model, appraising the significance of personal meaning and adaptation to one's own resources in order to cope with the disease (Barroilhet Diez, Forjaz, & Garrido Landívar, 2005; Folkman & Greer, 2000; Folkman, 2010; Holland, 2002; Watson, 2012), the need to be implemented by a specialist therapist and be acceptable to the patients, be holistic and generally short-term (Bulfone et al., 2009; Jacobsen & Jim, 2008, McDougall Miller & O'Callaghan, 2010; Myers-Virtue et al., 2015), and culturally adapted (Bro et al., 2018).

Within the same context, the presence of therapist and the relationship with her was valued by the interview participants as significant and meaningful, beyond any effects induced by the intervention, an observation highly supported by the findings of Bradt et al. (2015), Jacobsen and Jim (2008), and Hertrampf (2017). All women at the initial interviews spoke highly of their therapist's attitude and agreed that this element played a major role in their positive feedback, implying the need for high level professionalism and clinical expertise combined with the warmth of the personality of the therapist. At the same time, they all reported they would need more time "to open up" and feel fully acquainted to make the ultimate use of therapeutic time. These observations highlight the importance of a trustful relationship and therapeutic alliance between therapist and client. It is not the music per se that stands alone for a successful therapy course but also the good relationship and rapport with the therapist, expressed through the shared experiences of music and imagery and the discussions followed. This was important not only for a good therapy outcome, but in this case, it also helped the participants stay committed to the research process.

4.1.5. REFLECTIONS ON DESIGN AND TREATMENT OUTCOMES

The designs used for the two parts of this investigation had many advantages and allowed for many opportunities to assess a research project at various preliminary phases, both qualitative and quantitative. Findings of the individual experiences of the women participating in the feasibility study support the beneficial quantitative results of the pilot. Furthermore, they provided information about the participants' perspectives on the selected variables and their importance on their lives while coping with the disease. Women reported the experience as relaxing, inducing positive mood, giving chance to re-negotiate relationships with significant others and re-connect in a new way, facilitating connection with spiritual aspects. They also acknowledged the importance of having GIM outside the hospital. Although it was not part of the research questions, some reflected on the preference of individual work as opposed to group work for it gives personal space, respect for individual needs, and privacy. This view agrees with Hertrampf (2017) for the appropriateness of an individual approach over the group for such a sensitive population. Women's affirmation was important to get an understanding of their needs as described by them, especially in such a small study when quantitative psychometric questionnaires do not often show statistically significant changes due to small sample size.

The design of second part of the investigation (RCT pilot study) and its quantitative results as discussed below were based on the results of the feasibility, serving to further explore and validate them in a more rigorous way. It functioned as a replicated, mini model of a future RCT, an underpowered trial that may help us to clarify the methodological difficulties and changes need to be made in order to design a well-working protocol (Abbott, 2014). The pilot highlighted more issues on recruitment, instruments, inclusion and exclusion criteria, cultural considerations, number and frequency of sessions, attrition, and useful additions or revisions towards a bigger scale research study. It corroborated the difficulties with frequency and scheduling of sessions, previously detected in the feasibility, raising considerations not only for clinicians but also for researchers who pursue projects in such a clinical area (Hanser et al., 2006). Another interesting issue is the observation regarding attrition rates relevant to patients' capacity to participate according to the disease stage.

The three core themes extracted from the feasibility study and the interviews, namely mood, hope, and fatigue, were used for developing the research questions of the RCT pilot. Although the sample of the two studies is not comparable, the findings in the two studies were similar. Analysis of the data of the two studies show an increased level of hope after the intervention, as seen from patients' perceived experience, Likert scale for Hope, VAS-H, and the medium effect size of the HHI questionnaire. This finding confirms the capacity of GIM to activate positive coping mechanisms (Bonny, 1997, 2002c; Burns et al., 2018; McKinney & Grocke, 2016; Short, 2016; Summer, 2011), making it a useful tool in psychotherapeutic supportive practice with fragile populations.

The most reported outcome of the feasibility was the positive change in fatigue levels with most women describing themselves as less tired and more relaxed after the GIM sessions and the Likert scales for fatigue confirming these statements for the three of them. The VAS-F results of the RCT pilot also confirmed significant positive changes for the intervention group with decreased levels of fatigue after GIM. The CFS questionnaire did not manage to capture significant changes, despite a medium effect size. Whether fatigue can be positively influenced by GIM is uncertain, but the combination of feedback from the interviews and the psychometric findings suggest that it might be possible to influence this through GIM. Investigating this in a larger sample size and with perhaps a different choice of instruments is needed.

Moreover, the results of the VAS scales of the RCT pilot study, illuminate an interesting curve with an initial intensifying of the symptomatology which gradually improves over time, consistent with McKinney et al., (1997) in a study of health adults; fatigue seems to be worsening before improving and hope levels being lower before they increased. The only explanation here is speculative. Maybe the fact that the participants were chosen in a "cancer research group" raised their distress in the beginning as they may have felt stigmatized, facing the realization of their condition, or being distressed about what this "research" may be and what it may reveal. As they went along, they became acclimated, gaining more acceptance and confidence; therefore, the curves started getting improved.

Another change was the positive report on better mood after GIM session, as described by the four participants of the feasibility. These changes could not be confirmed by HADS or POMS-brief questionnaire used in the pilot study, a

fact that is not fully in agreement with previous findings by other relevant studies reporting positive mood changes (Bonde, 2005; Bro et al., 2018; Hertrampf, 2017); however, POMS showed a medium effect size which is promising for such a small size number. On the contrary, the control group in the pilot appeared to have slightly better mood after 6 weeks, perhaps due to their elevated levels of mood disturbance at pretest. This might be an indication that mood is determined by other situations and factors, irrelevant to treatment, but it may also be related to the observation by Burns et al. (2018) that patients receiving MI sessions during the period of chemotherapy treatment engage more emotionally; however, such broad emotional experience may also contain higher level of distress.

Finally, the correlation analysis between the three variables (hope, mood, fatigue; presented in Article 3) showed that the more tired the participants felt the less hopeful they were, whereas the lower the mood and hope, the higher the fatigue. This inter-dependence between the study variables justify part of the rationale of this study: it shows that there is indeed an important interplay between specific QoL factors and highlights the importance of addressing these within a psychological perspective, thus giving an active role to GIM to explore such dimensions that some of them have not been directly addressed and systematically explored previously in the GIM literature.

4.2. LIMITATIONS AND RECOMMENDATIONS

This study included an heterogenous sample of women at first diagnosis and advanced cancer patients. One of the reasons was that we wanted to be inclusive, but another practical reason was the limited number of patients drawn from one hospital only. Future research may focus on a more homogenous group of patients, to investigate whether specific emotional or behavioral patterns and responses are created that may be relevant to the stage of the disease of a specific target group. This may also have an effect in attrition rates, since three of the participants dropped out during this research because of health deterioration and death. If a future study targets advanced cancer and palliative care population, it would be important to consider limited number of sessions to reduce risk of high attrition rates (Warth et al., 2015) In such case, number of sessions and frequency require further investigation, since the researcher would need to balance this with having sufficient sessions to lead to change. Other cultural or social characteristics

may also be considered, such as age, economic, or education status, to draw more targeted conclusions. It is also recommended that GIM can be tested with other cancer populations, not exclusively gynecologic and breast cancer.

The small sample size limits the power of the study to identify significant changes in the variables. The nonsignificant results contradict findings of previous studies. However, medium effects sizes for the variables hope, mood, and fatigue point towards some clinical significance at a preliminary level, which can be explored in large scale studies. Narrow sensitivity of standardized instruments to the GIM process or inappropriateness of the instruments due to limited selection options, could also be given some consideration in future research designs.

One of the outcomes of this first GIM study to explore hope directly, was the capacity of GIM to help increase the levels of hope for women during chemotherapy treatment as shown from the interviews' findings, the Likert Scales, VAS, and the medium effect size of HHI. This aspect could be further explored quantitatively in larger scale protocols and through qualitative interviews and analysis of session transcripts that could possibly highlight trends in the imagery experience related to the "hope" agent. Women also found resources through spiritual experiences, an aspect that is worth exploring further since many patients often resort to spirituality to gain strength and hope.

Similarly, positive tendency of GIM to relieve cancer-related fatigue is important to acknowledge, as seen from Likert scales, VAS, interviews, and the medium effect size of the CFS questionnaire. Although the participants in the feasibility reported better mood in their interviews, HADS and POMS did not confirm this, despite POMS' medium effect size. Further investigation on fatigue and mood levels must be undertaken both with quantitative and qualitative means to explain the inconsistency and disagreement between participants' reported experience and VAS results and standardized questionnaires that now point in different directions.

Execution of this study faced barriers in terms of recruitment and treatment consistency due to the participants' physical conditions and limited resources. This is an important consideration both for clinicians, who must always be flexible and adjust to the current patient's needs and for researchers who must take into account these factors upon scheduling larger research protocols.

Treatment offered must remain short-term with a limited number of sessions so that it is manageable, yet sufficiently long to have effect. One-to-one therapy sessions are preferable in this situation, as they are much easier to coordinate at an individual level rather than in a group setting, in terms of scheduling and facilities. In addition, individual therapy gives more space for intimate sharing in a non-judgmental setting, an important consideration when working with fragile population or people who are not used to disclosure in a therapeutic context.

Cultural perspectives are related to the above observation and must also be acknowledged. Specific mentalities and attitudes may cause problems with common issues encountered in research such as recruitment, randomization process, or making good use of the therapeutic space, especially for participants who need more time to trust the process. In agreement with Wärja (2018), perhaps an initial interview with therapist before work begins could help to build alliance and make this short-term therapy even more beneficial for them.

Music in this study was based exclusively on original, core music programs of the Helen Bonny GIM method, modified to include small and medium container music with supportive, and mixed supportive-challenging qualities. However, future research could explore possibilities of using other music with similar qualities, including music from other styles and genres, classical, soundtrack or new age music, or ethnic music with cultural influences. Music may be formulated in a sequence to create a short program, or, a single piece of music may be repeated more than one time, according to Summer's model on repetitive music listening (Summer, 2011).

Finally, I fully agree with Hertrampf and Wärja (2017) and Jacobsen and Jim (2008) that in order to implement such a method in oncology in Greece or even other countries, there is a need for a tailored training in Receptive Music Therapy in Medicine framework, addressed to health professionals, nurses, and counsellors in cancer care because of the promising benefits of our methods to offer support, hope, and soothing.

4.3. CREATING A CLINICAL MODEL

At this stage, I would like to take the opportunity to integrate my experience and my learnings from this study into a proposed adapted model for working with GIM with patients during a course of active adjuvant treatment for cancer. This is a model based on research results as described above, combined with my own experience as a researcher and clinician. I am proposing this model as an inspiration for clinical integration with important recommendations and suggestions for those GIM therapists intending to expand their practice in this medical area.

As seen in Figure 4-2, the main principal of this model is that it presupposes working within an integrative medical model that allows for a psycho-oncology framework to cancer care and the use of complementary psychological interventions as treatment approaches, preferably in a one-to-one therapy setting, when feasible. GIM has a place as a supportive psychotherapy intervention that acknowledges the multi-dimensional aspects and the complexity of cancer medical treatment and can be used with specific aims related to the needs created under this special condition. GIM must be acknowledged for its benefits by the multidisciplinary team working in cancer care and must be offered by a specialist healthcare professional (Jacobsen & Jim, 2008).

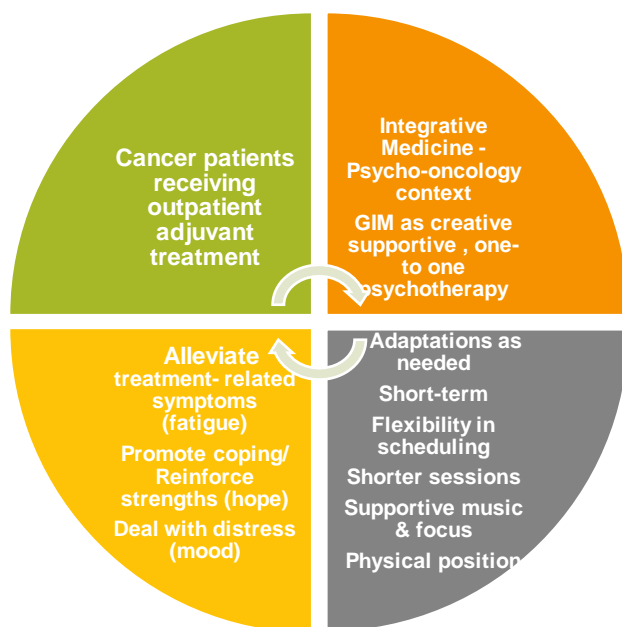


Figure 4-2. A working model for GIM during a course of active cancer treatment

I am proposing that, for GIM to be viable with this clinical population, certain adaptations must be made with regards to flexibility in practical issues and scheduling; the duration of session and overall length of therapy; the dynamics and length of music; the use of a supportive opening focus; occasionally with considerations of the physical position; and constant adjustments to physical and mental capacities of the patient. By doing so, GIM can help improve or support crucial aspects of patients' life-issues during a chemotherapy period; it can help the patient cope with the struggle in a more manageable way by enhancing inner strengths that promote coping, by mitigating treatment-related symptoms having psychological as well as physical implications (such as fatigue), and by providing safe space to relieve emotional distress.

4.4. CONCLUSION

This two-part investigation took place for the purposes of indicating whether the GIM intervention will be worthwhile for conducting a future main RCT study, establishing any key components necessary for designing further steps towards research, and enriching clinical practice. In this epilogue, based on the substantial results and observations of this study, one can conclude that GIM can be used as a complementary, supportive psychological therapy during a course of active cancer treatment. GIM has a good potential in providing psychological and physical support when most needed, especially by boosting levels of hope and helping patients feel more relaxed. However, working with such a fragile population requires patience and flexibility of the clinicians, and a mature therapeutic stance that allows for monitoring and constant adjustments to individual patients' current needs. Although larger scale research and RCT trials are recommended to confirm the preliminary findings of this investigation, the instability of the population created by their medical condition may cause practical, organizational, and management problems in conducting research, especially small-scale projects with limited resources and funds. Well-funded projects equipped with resources and adequate personnel may possibly overcome such challenges, if these aspects are considered well in advance. Finally, GIM can be beneficial for cancer patients, and I hope more hospitals in Greece will consider providing the facilities to host such interventions in the future.

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Appendix A. Ethics approval for the feasibility study



ΕΘΝΙΚΟ ΚΑΙ ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ – ΑΡΕΤΑΙΕΙΟ ΝΟΣΟΚΟΜΕΙΟ

ΕΠΙΤΡΟΠΗ ΕΡΕΥΝΑΣ

Πρόεδρος : Ι. Βασιλείου

Γραμματέας : Γ. Φραγκουλιδης

Μέλη : Η. Λιανός, Λια-Ευαγγ Μουλοπούλου, Ευγ Κουσκούνη
Ευθ Δεληγεώργη, Ι. Σιαφάκα

Αθήνα 31/01/2017

Προς την Κυρία
Παπανικολάου Ευαγγελία
Μουσικοθεραπεύτρια-Ψυχοθεραπεύτρια
Αρεταίειο νοσοκομείο

Κυρία Παπανικολάου

Η Επιτροπή Έρευνας του Αρεταείου νοσοκομείου στη σημερινή της συνεδρίαση, η οποία έγινε παράλληλα και με την Επιτροπή Ηθικής και Δεοντολογίας, μελέτησε την αίτηση σας για το ερευνητικό πρωτόκολλο με τίτλο :

Η επίδραση της μουσικοθεραπείας Guided Imagery & Music ως συμπληρωματική ψυχολογική παρέμβαση σε γυναίκες σε θεραπεία για γυναικολογικό καρκίνο

Η επιτροπή κάνει αποδεκτό το αίτημα σας με τις εξής προϋποθέσεις: να μην έχετε οικονομικές απαιτήσεις για την εκτέλεση του, να είναι σύμφωνο με τη νομοθεσία και να έχετε κάλυψη αστικής ευθύνης. Για τις κλινικές μελέτες να υπάρχει ειδικό έντυπο συναίνεσης του αρρώστου.

Το αίτημα σας να αποσυρθεί το πρωτόκολλο γίνεται δεκτό

Το καταχώρισε στο αρχείο της με τον αριθμό:

ΕΕ-2/01/31-01-2017

Ο Πρόεδρος

Ι. Βασιλείου

Appendix B. Ethics approval for the RCT pilot



ΕΘΝΙΚΟ & ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ – ΑΡΕΤΑΙΕΙΟ ΝΟΣΟΚΟΜΕΙΟ
ΕΓΚΡΙΣΗ ΕΠΙΤΡΟΠΗΣ ΕΡΕΥΝΑΣ

ΕΠΙΤΡΟΠΗ ΕΡΕΥΝΑΣ
 ΑΡΕΤΑΙΕΙΟΥ
 ΝΟΣΟΚΟΜΕΙΟΥ

Αθήνα, 19/06/2018

Προς
 Κα Ευαγγελία Παπανικολάου

Κυρία Παπανικολάου

ΠΡΟΕΔΡΟΣ:
 Γ. Πολυμενέας

Η Επιτροπή Έρευνας του Αρεταείου Νοσοκομείου, στη Συνεδρίαση η οποία έγινε παράλληλα και με την Επιτροπή Ηθικής και Δεοντολογίας, μελέτησε την αίτησή σας για το Ερευνητικό Πρωτόκολλο με τίτλο:

ΓΡΑΜΜΑΤΕΑΣ:
 Γ. Φραγκουλίδης

«Η επίδραση της μουσικοθεραπείας Guided Imagery and Music (GIM) ως συμπληρωματική ψυχολογική παρέμβαση για γυναίκες σε θεραπεία γυναικολογικού καρκίνου και καρκίνου του μαστού.»

ΜΕΛΗ:
 Ε. Δεληγεώργλου
 Ε. Κουσκούνη
 Λ. Ε. Μουλοπούλου
 Ι. Σιαφάκα
 Χ. Παπαδημητρίου

Η Επιτροπή κάνει αποδεκτό το αίτημά σας υπό τις εξής προϋποθέσεις: να μην υπάρχουν οικονομικές απαιτήσεις για την εκτέλεσή του, να είναι σύμφωνο με τη Νομοθεσία και να υπάρχει από μέρους σας κάλυψη αστικής ευθύνης. Επίσης για τις Κλινικές Μελέτες να υπάρχει ειδικό έντυπο συναίνεσης του ασθενούς.

Η έγκριση για το Ερευνητικό σας Πρωτόκολλο καταχωρήθηκε στο Αρχείο της Επιτροπής Έρευνας με τον αριθμό: 62/19-06-18

Ο Πρόεδρος

 Καθηγητής Γεώργιος Ε. Πολυμενέας

Appendix C. Informed consent form- Feasibility study

Φόρμα συγκατάθεσης στην έρευνα με τίτλο:

«Η επίδραση της δεκτικής μουσικοθεραπείας Guided Imagery & Music (GIM) κατά το στάδιο της θεραπείας για γυναικολογικό καρκίνο»

Όνομα ερευνητή: Ευαγγελία Παπανικολάου, Υπ. Δρ. Μουσικοθεραπείας, Παν. Aalborg, Δανία

Ονομάζομαι Ευαγγελία Παπανικολάου, και είμαι μουσικοθεραπεύτρια, θεραπεύτρια GIM και εκπαιδευτρια, και εκπονώ διδακτορική διατριβή στο Πανεπιστήμιο Aalborg της Δανίας (τμήμα Διεθνών Διδακτορικών Σπουδών Μουσικοθεραπείας, Σχολή Ψυχολογίας και Επικοινωνίας). Είμαι η βασική ερευνήτρια σε αυτή τη μελέτη στην οποία συμμετέχουν και συνεργάτιδές μου, ψυχολόγοι και θεραπεύτριες GIM που θα πραγματοποιήσουν τις αρχικές συνεντεύξεις και τις θεραπευτικές συνεδρίες.

Σκοπός της έρευνας: Σας προσκαλώ να λάβετε εθελοντικά μέρος στην έρευνά μου, η οποία αποτελεί το θέμα της μελέτης του διδακτορικού μου. Ενδιαφέρομαι να μάθω περισσότερα γύρω από την χρησιμότητα και την εφαρμογή της μουσικοθεραπείας GIM σε γυναίκες με γυναικολογικό καρκίνο κατά τη διάρκεια της χημειοθεραπείας. Θα εστιάσω περισσότερο στο κατά πόσο η μουσικοθεραπεία GIM μπορεί να βοηθήσει τις γυναίκες να μειώσουν το άγχος και την ένταση που προέρχεται από τη διάγνωση και θεραπεία της ασθένειας καθώς και την ποιότητα ζωής τους και τις παρενέργειες της χημειοθεραπείας, και πώς οι ίδιες αξιολογούν την επίδραση της μουσικοθεραπείας και τη διαδικασία, γενικότερα. Τα αποτελέσματα της έρευνας ενδέχεται να συμπεριληφθούν σε επιστημονικές δημοσιεύσεις ή συνέδρια.

Η έρευνα αποτελείται από την αρχική συνέντευξη στην οποία θα συμπληρώσετε δημογραφικές πληροφορίες και να συμπληρώσετε δύο ερωτηματολόγια (εκτίμηση χρόνου 5-10'). Κατόπιν, θα ακολουθήσετε έξι ατομικές συνεδρίες μουσικοθεραπείας GIM διάρκειας έως 50' η καθεμία, για διάστημα 6 εβδομάδων (μία συνάντηση την εβδομάδα) . Πριν και μετά από κάθε συνεδρία θα ερωτηθείτε πώς νιώθετε. Στο τέλος των συνεδριών, θα συμπληρώσετε ξανά τα δύο ερωτηματολόγια και μετά από 10 περίπου μέρες θα υπάρξει μια ακόμα συνάντηση συζήτησης/αξιολόγησης της εμπειρίας διάρκειας 20-40' η οποία θα ηχογραφηθεί για λόγους ευκρίνειας και θα πραγματοποιηθεί από εμένα, ως βασική ερευνήτρια του προγράμματος.

Ποια είναι η διαδικασία; Οι θεραπευτικές συναντήσεις (της αρχικής/τελικής συνέντευξης όσο και των έξι θεραπευτικών συνεδριών) θα πραγματοποιηθούν σε ειδικά διαμορφωμένους χώρους στο Αρεταίειο Νοσοκομείο ή σε συνεργαζόμενους φορείς,

όπως συμφωνηθεί στην αρχική συνάντηση. Ο χώρος θα είναι ήσυχος, και θα υπάρχει κρεβάτι/καναπές, μαξιλάρι, ηχοσύστημα και καρέκλες. Η συνεδρία θα ξεκινάει με τη συμπλήρωση των ερωτηματολογίων, θα προχωρά με συζήτηση γύρω από τα θέματα που απασχολούν τη γυναίκα την παρούσα στιγμή και αφού προσδιοριστεί έτσι ο στόχος της συνεδρίας, η συμμετέχουσα θα ξαπλώνει αναπαυτικά στον καναπέ-κατά προτίμηση με τα μάτια κλειστά. Η θεραπεύτρια θα κάνει μια ολιγόλεπτη σωματική χαλάρωση (3-4 λεπτά) και στη συνέχεια, θα ξεκινήσει η μουσική. Κατά τη διάρκεια της μουσικής ακρόασης, η συμμετέχουσα ενθαρρύνεται να εκφράσει οτιδήποτε της φέρνει η μουσική στο μυαλό, συναισθήματα, σωματικές αισθήσεις, νοητικές και νοερές εικόνες, σκέψεις, κλπ. Η θεραπεύτρια υποστηρίζει ή ενθαρρύνει την εμπειρία, χωρίς να την κατευθύνει. Παράλληλα, καταγράφει όσα ειπώθηκαν κατά τη διάρκεια της μουσικής. Στο τέλος της συνεδρίας, το υλικό αυτό δίνεται στη γυναίκα και η θεραπεύτρια κρατά αντίγραφο αυτού για τους σκοπούς της έρευνας. Η διάρκεια της μουσικής είναι έως 20 λεπτά, ανάλογα με τις ατομικές ανάγκες της κάθε γυναίκας. Όταν τελειώνει η μουσική, η θεραπεύτρια προσκαλεί τη συμμετέχουσα να έρθει σε όρθια θέση και να συζητήσουν την εμπειρία.

Εμπιστευτικότητα: Όλες οι πληροφορίες από τις συνεδρίες θα κρατηθούν ανώνυμες και εμπιστευτικές. Ανώνυμες σημαίνει ότι το όνομα ή άλλες πληροφορίες ταυτότητας των συμμετεχόντων γυναικών δεν θα κοινοποιηθούν, ενώ το περιεχόμενο και οι λεπτομέρειες της διαδικασίας θα παραμείνουν μεταξύ των συνεργατών της έρευνας. Εμπιστευτικές σημαίνει ότι κάθε όνομα θα αντικατασταθεί με έναν αριθμό και όταν τα αποτελέσματα της έρευνας δημοσιευτούν, τα ονόματα θα αντικατασταθούν με ψευδώνυμα και τα δημογραφικά χαρακτηριστικά θα αλλοιωθούν ελαφρώς για να διαφυλαχτεί η ιδιωτικότητα.

Οφέλη και ρίσκα: Η συμμετοχή στην έρευνα μπορεί να μην έχει άμεσο όφελος σε εσάς. Το μεγαλύτερο όφελος -ως αποτέλεσμα της συμμετοχής σας στην έρευνα- είναι η βοήθεια που μας προσφέρετε να εμπλουτίσουμε και να βελτιώσουμε τις γνώσεις μας γύρω από το πώς να διεκπεραιώσουμε τις πλέον ευεργετικές θεραπείες και παρεμβάσεις και τον καταλληλότερο τρόπο εφαρμογής του GIM σε γυναίκες με γυναικολογικό καρκίνο.

Παρότι δεν αναμένεται σωματική ή ψυχολογική βλάβη συνδεδεμένη με το GIM, μπορεί να νιώσετε θετικά ή αρνητικά συναισθήματα ή αισθήσεις στο άκουσμα κάποιου μουσικού κομματιού. Ωστόσο, δεδομένου ότι οι όποιες πιθανές έντονες αντιδράσεις στη μουσική αποτελούν μέρος της θεραπευτικής διαδικασίας, θα υπάρχει χώρος και χρόνος από τον θεραπευτή να γίνει η κατάλληλη διαχείριση τους, να εκφραστούν οι εμπειρίες και να υποστηριχτούν κατάλληλα. Σε περίπτωση που υπάρξει σοβαρός λόγος και ένταση κατά την τελευταία θεραπευτική συνάντηση, θα δοθεί η δυνατότητα ενός επιπλέον θεραπευτικού ραντεβού ή, ο θεραπευτής θα σας προτείνει κάποιο κέντρο ψυχολογικής υποστήριξης κατάλληλο για τις ανάγκες σας. Παρόλα αυτά, σε περίπτωση που η συμμετέχουσα αποφασίσει να μη συνεχίσει σε οποιαδήποτε χρονική

στιγμή, διατηρεί το δικαίωμα να διακόψει χωρίς ρήτρα. Δεν υπάρχει κόστος ή ανταμοιβή για τη συμμετοχή στο πρόγραμμα.

Μπορείτε να με καλέσετε στα τηλέφωνα 6972234171, 2108025536 (Ευαγγελία Παπανικολάου) ή στο evangelia@sonora.gr οποιαδήποτε στιγμή χρειαστείτε παραπάνω πληροφορίες για την έρευνα. Η έρευνα παρακολουθείται από τους δύο ακαδημαϊκούς επόπτες μου, Ass.Prof. Niels Hannibal, Aalborg University, Δανία (hannibal@hum.aau.dk) και Prof. Dr. Cathy McKinney, Appalachian State University, USA (mckinneych@appstate.edu).

Ως συμμετέχουσα, δηλώνω: Όλες οι ερωτήσεις μου και οι ανησυχίες μου σχετικά με αυτή την έρευνα έχουν αντιμετωπιστεί και απαντηθεί. Επιλέγω να συμμετάσχω εθελοντικά σε αυτή την έρευνα. Βεβαιώνω ότι είμαι τουλάχιστον 18 ετών.

ΟΝΟΜΑ

ΥΠΟΓΡΑΦΗ

Όνομα ερευνήτριας

ΕΥΑΓΓΕΛΙΑ ΠΑΠΑΝΙΚΟΛΑΟΥ

Υπογραφή ερευνήτριας

Ημερομηνία

Η παρούσα συγκατάθεση έχει ισχύ τριών μηνών από την ημερομηνία υπογραφής της

Appendix D. Informed consent form- RCT Pilot

Φόρμα συγκατάθεσης στην έρευνα με τίτλο:

«Η επίδραση της δεκτικής μουσικοθεραπείας Guided Imagery & Music (GIM) σε σύγκριση με τη λεκτική θεραπεία για γυναίκες στο στάδιο της χημειοθεραπείας»

Όνομα ερευνητή: Ευαγγελία Παπανικολάου, Υπ. Δρ. Μουσικοθεραπείας, Παν. Aalborg, Δανία

Ονομάζομαι Ευαγγελία Παπανικολάου, είμαι μουσικοθεραπεύτρια, θεραπεύτρια GIM και εκπαιδευτρια, και εκπονώ διδακτορική διατριβή στο Πανεπιστήμιο Aalborg της Δανίας (τμήμα Διεθνών Διδακτορικών Σπουδών Μουσικοθεραπείας, Σχολή Ψυχολογίας και Επικοινωνίας) η οποία πραγματοποιείται στην Ελλάδα με άδεια της επιτροπής έρευνας του Αρεταλείου Νοσοκομείου και σε συνεργασία με τους θεράποντες ιατρούς. Είμαι η βασική ερευνήτρια σε αυτή τη μελέτη στην οποία συμμετέχουν επίσης τρεις συνεργάτιδές μου, ψυχολόγοι και θεραπεύτριες GIM.

Σκοπός της έρευνας: Σας προσκαλώ να λάβετε εθελοντικά μέρος στην έρευνά μου, η οποία αποτελεί το θέμα της μελέτης του διδακτορικού μου. Ενδιαφέρομαι να μάθω περισσότερα γύρω από την χρησιμότητα και την εφαρμογή της μουσικοθεραπείας GIM σε σύγκριση με τη λεκτική θεραπεία, για γυναίκες με γυναικολογικό καρκίνο/καρκίνο μαστού κατά τη διάρκεια της χημειοθεραπείας. Τα αποτελέσματα της έρευνας θα συμπεριληφθούν σε επιστημονικές δημοσιεύσεις ή συνέδρια.

Η έρευνα αποτελείται από την αρχική συνέντευξη στην οποία θα συμπληρώσετε δημογραφικές πληροφορίες (μπορείτε να μην απαντήσετε σε οποιαδήποτε ερώτηση της δημογραφικής φόρμας) και να συμπληρώσετε τρία ερωτηματολόγια (εκτίμηση χρόνου 5-10'). Κατόπιν, θα έχετε τυχαία επιλεγθεί είτε να συμμετάσχετε σε έξι ατομικές συνεδρίες μουσικοθεραπείας GIM (μία ανά βδομάδα) είτε σε δύο συνεδρίες λεκτικής συμβουλευτικής θεραπείας πριν και μετά τις 6 βδομάδες. Όλες οι συμμετέχουσες θα συμπληρώσουν δύο απλές ερωτήσεις για το πώς νιώθουν μια φορά τη βδομάδα για 6 βδομάδες και την τελευταία βδομάδα θα συμπληρώσουν ξανά τα τρία αρχικά ερωτηματολόγια. Τα ερωτηματολόγια θα δοθούν εξ αρχής στις συμμετέχουσες της ομάδας λεκτικής θεραπείας και κατά τη διάρκεια των εβδομαδιαίων συναντήσεων για τις συμμετέχουσες της μουσικοθεραπείας GIM.

Για τις συμμετέχουσες των 6 συνεδριών μουσικοθεραπείας, Οι συναντήσεις θα πραγματοποιηθούν στο γραφείο της θεραπεύτριας που βρίσκεται κοντά στην περιοχή της συμμετέχουσας, ή σε ειδικά διαμορφωμένο χώρο στο νοσοκομείο, όπως συμφωνηθεί στην αρχική συνάντηση. Ο χώρος θα είναι ήσυχος, και θα υπάρχει

κρεβάτι/καναπές, μαξιλάρι, ηχοσύστημα και καρέκλες. Η συνεδρία θα ξεκινάει με συζήτηση γύρω από τα θέματα που απασχολούν τη γυναίκα την παρούσα στιγμή και αφού προσδιοριστεί έτσι ο στόχος της συνεδρίας, η συμμετέχουσα θα ξαπλώνει αναπαυτικά στον καναπέ-κατά προτίμηση με τα μάτια κλειστά. Η θεραπεύτρια θα κάνει μια ολιγόλεπτη σωματική χαλάρωση (3-4 λεπτά) και στη συνέχεια, θα ξεκινάει η μουσική, ενδεχομένως με ένα αρχικό θέμα εστίασης (focus). Κατά τη διάρκεια της μουσικής ακρόασης, η συμμετέχουσα ενθαρρύνεται να εκφράσει οτιδήποτε της φέρνει η μουσική στο μυαλό, συναισθήματα, σωματικές αισθήσεις, νοητικές και νοερές εικόνες, σκέψεις, κλπ. Η θεραπεύτρια υποστηρίζει ή ενθαρρύνει την εμπειρία, χωρίς να την κατευθύνει. Παράλληλα, καταγράφει όσα ειπώθηκαν κατά τη διάρκεια της μουσικής. Στο τέλος της συνεδρίας, το υλικό αυτό δίνεται στη γυναίκα και η θεραπεύτρια κρατά αντίγραφο αυτού για τους σκοπούς της έρευνας. Η διάρκεια της μουσικής είναι έως 20 λεπτά, ανάλογα με τις ατομικές ανάγκες της κάθε γυναίκας. Όταν τελειώνει η μουσική, η θεραπεύτρια προσκαλεί τη συμμετέχουσα να έρθει σε όρθια θέση και να συζητήσουν την εμπειρία, και τέλος, συμπληρώνονται οι δύο ερωτήσεις της έρευνας.

Για τις συμμετέχουσες στη λεκτική υποστηρικτική θεραπεία: Για τις γυναίκες που έχουν τυχαία επιλεγθεί για τις συνεδρίες λεκτικής θεραπείας, θα λάβουν μια συνεδρία στην αρχή και μια στο τέλος των 6 βδομάδων με μία από τις θεραπεύτριες. Στη συνεδρία αυτή που θα πραγματοποιηθεί στο νοσοκομείο ή στο γραφείο της θεραπεύτριας θα έχουν την ευκαιρία να συζητήσουν ό,τι τις απασχολεί σχετικά με την υγεία και την εμπειρία τους, την αγωγή που παίρνουν ή οτιδήποτε άλλο τις απασχολεί.

Εμπιστευτικότητα: Όλες οι πληροφορίες από τις συνεδρίες θα κρατηθούν ανώνυμες και εμπιστευτικές. Ανώνυμες σημαίνει ότι το όνομα ή άλλες πληροφορίες ταυτότητας των συμμετεχόντων γυναικών δεν θα κοινοποιηθούν, ενώ το περιεχόμενο και οι λεπτομέρειες της διαδικασίας θα παραμείνουν μεταξύ των συνεργατών της έρευνας. Εμπιστευτικές σημαίνει ότι κάθε όνομα θα αντικατασταθεί με έναν αριθμό και όταν τα αποτελέσματα της έρευνας δημοσιευτούν, τα ονόματα θα αντικατασταθούν με ψευδώνυμα και τα δημογραφικά χαρακτηριστικά θα αλλοιωθούν ελαφρώς για να διαφυλαχτεί η ιδιωτικότητα.

Οφέλη και ρίσκα: Η συμμετοχή στην έρευνα μπορεί να μην έχει άμεσο όφελος σε εσάς. Το μεγαλύτερο όφελος -ως αποτέλεσμα της συμμετοχής σας στην έρευνα- είναι η βοήθεια που μας προσφέρετε να εμπλουτίσουμε και να βελτιώσουμε τις γνώσεις μας γύρω από το πώς να διεκπεραιώσουμε τις πλέον ευεργετικές θεραπείες και ψυχολογικές παρεμβάσεις για γυναίκες με καρκίνο.

Για τις συμμετέχουσες της μουσικοθεραπείας, παρότι δεν αναμένεται σωματική ή ψυχολογική βλάβη συνδεόμενη με τη μέθοδο, μπορεί να νιώσετε θετικά ή αρνητικά συναισθήματα ή αισθήσεις στο άκουσμα κάποιου μουσικού κομματιού. Ωστόσο, δεδομένου ότι οι όποιες πιθανές έντονες αντιδράσεις στη μουσική αποτελούν μέρος της θεραπευτικής διαδικασίας, θα υπάρχει χώρος και χρόνος από τον θεραπευτή να

γίνει η κατάλληλη διαχείριση τους, να εκφραστούν οι εμπειρίες και να υποστηριχτούν κατάλληλα.

Σε περίπτωση που υπάρξει σοβαρός λόγος και ένταση κατά την τελευταία θεραπευτική συνάντηση, θα δοθεί η δυνατότητα ενός επιπλέον θεραπευτικού ραντεβού ή, η θεραπεύτρια σας, θα σας προτείνει κάποιο κέντρο ψυχολογικής υποστήριξης κατάλληλο για τις ανάγκες σας. Παρόλα αυτά, σε περίπτωση που αποφασίσετε να μη συνεχίσετε σε οποιαδήποτε χρονική στιγμή, διατηρείτε το δικαίωμα να διακόψετε χωρίς ρήτρα. Δεν υπάρχει κόστος ή ανταμοιβή για τη συμμετοχή στο πρόγραμμα.

Μπορείτε να με καλέσετε στα τηλέφωνα 6972234171, 2108025536 (Ευαγγελία Παπανικολάου) ή στο evangelia@sonora.gr οποιαδήποτε στιγμή χρειαστείτε παραπάνω πληροφορίες για την έρευνα. Η έρευνα παρακολουθείται από τους δύο ακαδημαϊκούς επόπτες μου, Ass.Prof. Niels Hannibal, Aalborg University, Δανία (hannibal@hum.aau.dk) και Prof. Dr. Cathy McKinney, Appalachian State University, USA (mckinneych@appstate.edu) με τη συνεργασία του Καθ. Χ. Παπαδημητρίου και των λοιπών θεραπόντων ιατρών.

Ως συμμετέχουσα, δηλώνω: Όλες οι ερωτήσεις μου και οι ανησυχίες μου σχετικά με αυτή την έρευνα έχουν αντιμετωπιστεί και απαντηθεί. Επιλέγω να συμμετάσχω εθελοντικά σε αυτή την έρευνα. Βεβαιώνω ότι είμαι τουλάχιστον 18 ετών.

ΟΝΟΜΑ

ΥΠΟΓΡΑΦΗ

Όνομα ερευνήτριας

ΕΥΑΓΓΕΛΙΑ ΠΑΠΑΝΙΚΟΛΑΟΥ

Υπογραφή ερευνήτριας

Ημερομηνία

Η παρούσα συγκατάθεση έχει ισχύ τριών μηνών από την ημερομηνία υπογραφής της.

Appendix E. Demographics

Δημογραφικό ερωτηματολόγιο

A.A. _____ Ημερομηνία _____

1. Όνομα

2. Ηλικία τόπος μόνιμης
κατοικίας.....

3. Μορφωτικό επίπεδο

Βασική εκπαίδευση

☐

Μέση εκπαίδευση

☐

Ανώτατη εκπαίδευση

☐

4. Επαγγελματική κατάσταση

Εργαζόμενη

☐

Οικιακά

☐

Συνταξιούχος

☐

Άνεργη

☐

5. Οικογενειακή κατάσταση

Έγγαμη/σε σχέση

☐

Διαζευγμένη

☐

Άγαμη

☐

Χήρα

☐

6. Συνθήκες διαβίωσης (με ποιόν ζείτε;)

Μόνη

☐

Οικογένεια (με παιδιά)

☐

Σύζυγο

☐

Άλλον

☐

7. Διάγνωση (γυναικολογικός καρκίνος ή μαστού?)

8. Ημερομηνία αρχικής διάγνωσης

9. Είδος θεραπείας στο παρόν

ΧΜΘ

ΑΚΘ

10. Στάδιο θεραπείας, αριθμός ΧΜΘ/ΑΚΘ μέχρι σήμερα

11. Αριθμός υποτροπών/μεταστάσεων (αν υπάρχουν)

Appendix F. Recruitment sheet

Date	Women met in hospital (Names)	Women contacted via phone (names)	Rejected/not eligible and reason for rejection	Not interested/no-show (reason if given)

Appendix G. Session log

Client

initial session date

termination date

Screening

initial interview

FACT-G/HADS (before)

FACT-G/HADS (after)

post-interview

Date/day/time	Venue	Relaxation used/duration	Reasoning for relaxation choice	Music used/duration	Reasoning for music choice	Session duration	Focus (?)	Key images	VAS completed before/after session (check)
1 st									
2 nd									
3 rd									
4 th									
5 th									
6 th									

Therapist's comments:

1st)

2nd)

3rd)

4th)

5th)

6th)

Appendix H. Hospital Anxiety & Depression Scale (HADS)

PSYCHIATRIKI 18 (3), 2007

ΚΛΙΜΑΚΑ ΑΓΧΟΥΣ ΚΑΙ ΚΑΤΑΘΛΙΨΗΣ ΣΤΟ ΓΕΝΙΚΟ ΝΟΣΟΚΟΜΕΙΟ (HADS)

7

Νοσοκομειακή Μέτρηση Άγχους και Κατάθλιψης (HADS)

Όνομα:

Ημερομηνία:

Οι κλινικοί ιατροί είναι σε επίγνωση ότι τα συναισθήματα παίζουν ένα σημαντικό ρόλο στις περισσότερες ασθένειες. Αν ο/η κλινικός/ή ιατρός σας γνωρίζει σχετικά μ' αυτά τα συναισθήματα, θα είναι σε θέση να σας βοηθήσει περισσότερο.

Αυτό το ερωτηματολόγιο είναι σχεδιασμένο ώστε να βοηθήσει τον κλινικό ιατρό σας να γνωρίσει πώς αισθάνεστε. Διαβάστε κάθε παρακάτω ερώτημα και υπογραμμίστε την απάντηση η οποία είναι πλησιέστερη στα συναισθήματά σας της προηγούμενης εβδομάδας.

Αντιγράψτε τους αριθμούς οι οποίοι είναι τυπωμένοι στο περιθώριο του ερωτηματολογίου.

Μην προβληματίζεστε πολύ για τις απαντήσεις σας, η άμεση ανταπόκρισή σας σε κάθε ένα από τα ερωτήματα θα είναι πιθανότατα αντιπροσωπευτικότερη από μια μακρόχρονη και αναλυμένη απάντηση.

A	D		A
3	Νιώθω ανήσυχος ή τρομαγμένος	Νιώθω σαν να έχουν πέσει οι ρυθμοί μου	
2	Τον περισσότερο καιρό	Σχεδόν όλο τον καιρό	
1	Πολύ καιρό	Πολύ συχνά	
0	Από καιρό σε καιρό, περιστασιακά	Μερικές φορές	
	Καθόλου	Καθόλου	
	Εξακολουθώ να απολαμβάνω τα πράγματα που συνήθιζα να απολαμβάνω	Αντιμετωπίζω κάποιο συναισθημα φόβου σαν να έχω «πεταλούδες» στο στομάχι μου	
0	Σαφέστατα, στον ίδιο βαθμό	Καθόλου	0
1	Όχι στον ίδιο βαθμό	Περιστασιακά	1
2	Λίγο μόνο	Αρκετά συχνά	2
3	Καθόλου	Πολύ συχνά	3
	Αντιμετωπίζω κάποιο συναισθημα φόβου σαν να πρόκειται κάτι τρομακτικό να συμβεί	Έχασα το ενδιαφέρον για την εμφάνισή μου	
3	Ακριβώς, μάλιστα σε σοβαρό βαθμό	Ακριβώς	
2	Ναι, αλλά όχι τόσο σοβαρά	Δεν την φροντίζω όσο θα έπρεπε	
1	Ελάχιστα, αλλά δεν μ' ανησυχεί	Ίσως δεν την φροντίζω όσο θα έπρεπε	
0	Καθόλου	Την φροντίζω όπως πάντοτε	
	Μπορώ να γελώ και να βλέπω τη χαριτωμένη όψη των πραγμάτων	Νιώθω νευρικός κι ανήσυχος, σαν να πρέπει συνέχεια να κινούμαι	
0	Βεβαίως, έτσι όπως πάντα μπορούσα	Μάλιστα σε πολύ μεγάλο βαθμό	3
1	Μάλλον όχι τόσο, όπως στο παρελθόν	Σε αρκετά μεγάλο βαθμό	2
2	Σίγουρα όχι τόσο πολύ	Όχι σε τόσο μεγάλο βαθμό	1
3	Καθόλου	Καθόλου	0
	Ανήσυχος σκέψες περνούν από το μυαλό μου	Προσμένω με χαρά διάφορα πράγματα	
3	Πάρα πολύ καιρό	Τόσο όπως και στο παρελθόν	
2	Πολύ καιρό	Μάλλον λιγότερο από όσο συνήθιζα	
1	Όχι τόσο συχνά	Σίγουρα λιγότερο από ότι συνήθιζα	
0	Πολύ λίγο	Καθόλου	
	Νιώθω κεφάτος	Αντιμετωπίζω ακινησία συναισθηματα πανικού	
3	Ποτέ	Πράγματι πολύ συχνά	3
2	Όχι συχνά	Αρκετά συχνά	2
1	Μερικές φορές	Όχι τόσο συχνά	1
0	Τον περισσότερο καιρό	Καθόλου	0
A	D		A
	Μπορώ να κάθομαι άνετα και να νιώθω χαλαρωμένος	Μπορώ να απολαμβάνω ένα ενδιαφέρον βιβλίο ή ένα ραδιοφωνικό/τηλεοπτικό πρόγραμμα	
0	Ακριβώς	Συχνά	
1	Συνήθως	Μερικές φορές	
2	Όχι συχνά	Όχι συχνά	
3	Καθόλου	Πολύ σπάνια	

Τώρα ελέγξτε ότι έχετε απαντήσει σε όλες τις ερωτήσεις

ΣΥΝΟΛΟ

A D

Αυτή η φόρμα μπορεί να αναπαραχθεί για χρήση, μέσα στο πλαίσιο των κανόνων αγοράς και μόνο σύμφωνα με τους όρους που αναφέρονται στη συμφωνία όσων από τον εκδότη, HADS copyright © R.P. Snaith and A.S. Zigmond, 1983, 1992, 1994. Τα στοιχεία της φόρμας καταχώρησης έχουν δημοσιευθεί πρωτότυπες στην Acta Psychiatrica Scandinavica, 67, 361-370, πνευματική ιδιοκτησία © (copyright ©) Munksgaard International Publishers Ltd, Copenhagen, 1983. Δημοσιεύθηκε από την Εταιρεία nferNelson Pub Co Ltd, 414 Chiswick High Road, London W4 5TF, UK. Με την επιφύλαξη παντός δικαιώματος, Η Εταιρεία nferNelson είναι μέλος του ομίλου Granada Learning Limited και ανήκει στην Εταιρεία ITV plc HADS Greek.

Appendix I. Functional Assessment for Cancer Therapy (FACT-G)

FACT-G (Version 4)

Θα βρείτε παρακάτω έναν κατάλογο από προτάσεις που άλλοι, με την ίδια νόσο όπως εσείς, θεωρούν σημαντικές. Παρακαλούμε βάλτε σε κύκλο ή σημειώστε έναν αριθμό ανά γραμμή για να υποδείξετε την απάντησή σας όσον αφορά τις τελευταίες 7 ημέρες.

ΠΡΟΣΩΠΙΚΗ ΦΥΣΙΚΗ ΚΑΤΑΣΤΑΣΗ		καθόλου	λίγο	κάπως	πολύ	πάρα πολύ
GP1	Μου λείπει ζωντάνια	0	1	2	3	4
GP2	Έχω ναυτία	0	1	2	3	4
GP3	Εξαιτίας της φυσικής μου κατάστασης, έχω πρόβλημα στο να ανταποκριθώ στις ανάγκες της οικογένειάς μου.....	0	1	2	3	4
GP4	Έχω πόνους	0	1	2	3	4
GP5	Ενοχλούμαι από τις παρενέργειες της θεραπείας μου	0	1	2	3	4
GP6	Νιώθω άρρωστος/η	0	1	2	3	4
GP7	Αναγκάζομαι να μένω στο κρεβάτι.....	0	1	2	3	4

ΚΟΙΝΩΝΙΚΗ/ΟΙΚΟΓΕΝΕΙΑΚΗ ΚΑΤΑΣΤΑΣΗ		καθόλου	λίγο	κάπως	πολύ	πάρα πολύ
GS1	Νιώθω κοντά στους φίλους μου	0	1	2	3	4
GS2	Η οικογένειά μου μου προσφέρει συναισθηματική συμπαράσταση.....	0	1	2	3	4
GS3	Υποστηρίζομαι από τους φίλους μου	0	1	2	3	4
GS4	Η οικογένειά μου έχει αποδεχθεί την ασθένειά μου ...	0	1	2	3	4
GS5	Είμαι ικανοποιημένος/η με την επικοινωνία που έχω με την οικογένειά μου όσον αφορά την ασθένειά μου.	0	1	2	3	4
GS6	Αισθάνομαι κοντά στον/στη σύντροφό μου (ή στο άτομο που κυρίως μου συμπαραστέκεται)	0	1	2	3	4
G1	Ανεξάρτητα από το επίπεδο της σημερινής σας σεξουαλικής δραστηριότητας, παρακαλούμε απαντήστε στην ακόλουθη ερώτηση. Εάν προτιμάτε να μην την απαντήσετε, σημειώστε με Χ το κουτάκι αυτό <input type="checkbox"/> και συνεχίστε στην επόμενη ενότητα					
GS7	Είμαι ικανοποιημένος/η με τη σεξουαλική μου ζωή....	0	1	2	3	4

FACT-G (Version 4)

Παρακαλούμε βάλτε σε κύκλο ή σημειώστε έναν αριθμό ανά γραμμή για να υποδείξετε την απάντησή σας όσον αφορά τις τελευταίες 7 ημέρες.

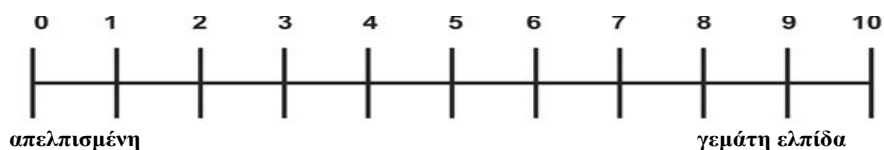
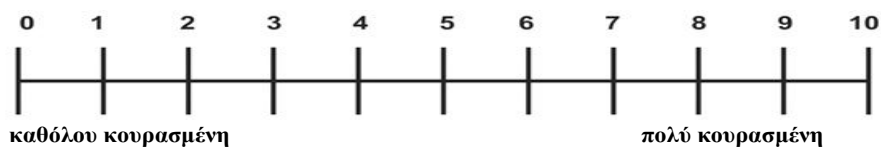
	ΣΥΝΑΙΣΘΗΜΑΤΙΚΗ ΚΑΤΑΣΤΑΣΗ	καθόλου	λίγο	κάπως	πολύ	πάρα πολύ
GE1	Αισθάνομαι θλίψη	0	1	2	3	4
GE2	Είμαι ικανοποιημένος/η με τον τρόπο που αντιμετωπίζω την ασθένειά μου	0	1	2	3	4
GE3	Χάνω τις ελπίδες μου στη μάχη με την ασθένειά μου	0	1	2	3	4
GE4	Αισθάνομαι νευρική/ότητα	0	1	2	3	4
GE5	Ανησυχώ ότι θα πεθάνω	0	1	2	3	4
GE6	Ανησυχώ ότι η κατάστασή μου θα χειροτερεύει	0	1	2	3	4

	ΓΕΝΙΚΗ ΙΚΑΝΟΤΗΤΑ ΛΕΙΤΟΥΡΓΙΚΟΤΗΤΑΣ	καθόλου	λίγο	κάπως	πολύ	πάρα πολύ
GF1	Είμαι σε θέση να εργαστώ (συμπεριλάβετε την εργασία στο σπίτι)	0	1	2	3	4
GF2	Η εργασία μου (συμπεριλάβετε την εργασία στο σπίτι) με ικανοποιεί	0	1	2	3	4
GF3	Μπορώ και χαίρομαι τη ζωή μου	0	1	2	3	4
GF4	Αποδέχομαι την ασθένειά μου	0	1	2	3	4
GF5	Κοιμάμαι καλά	0	1	2	3	4
GF6	Απολαμβάνω αυτά που συνήθως κάνω για διασκέδαση/αναψυχή	0	1	2	3	4
GF7	Είμαι ικανοποιημένος/η με την ποιότητα ζωής μου αυτή τη στιγμή	0	1	2	3	4

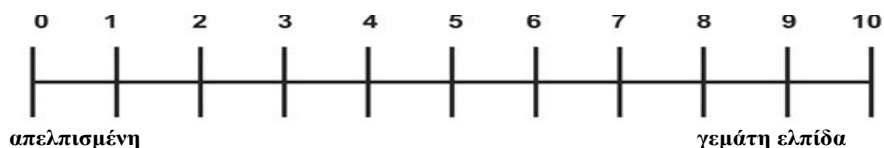
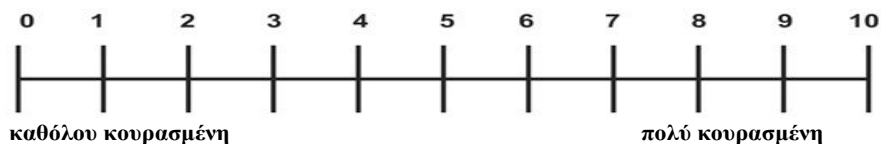
Appendix J. 10-point Likert scales for Fatigue and Hope

LIKERT SCALES FOR FATIGUE AND HOPE

Πριν τη συνεδρία



Μετά τη συνεδρία



Appendix K. Interview guide (Greek)

Οδηγός Συνέντευξης

1. Αρχικό κίνητρο-τι σας έκανε να θέλετε να συμμετάσχετε σε αυτό το πρόγραμμα;
2. Πως ήταν η εμπειρία σας σε γενικές γραμμές;
3. Πώς θα αξιολογούσατε τη δομή αυτού του προγράμματος; Για παράδειγμα, ο τρόπος που έχει στηθεί, πρακτικά ζητήματα και λεπτομέρειες, ο χώρος, συχνότητα και διάρκεια συνεδριών, αριθμός συνεδριών, κάτι άλλο;
4. Μπορείτε να πείτε λίγο πιο συγκεκριμένα για την εμπειρία σας με τη μουσικοθεραπεία GIM; Πως ήταν για εσάς και με ποιους τρόπους;
 - Πράγματα που σας άρεσαν ή δε σας άρεσαν;
 - Πως ήταν το γεγονός ότι κάνατε μουσικοθεραπεία κατά τη διάρκεια των χημειοθεραπειών σας;
 - Πείτε λίγα πράγματα για το πώς η μουσική λειτούργησε για σας? Τι ρόλο έπαιξε για σας? Υπήρχε κάτι που σας άρεσε ή που δε σας άρεσε σχετικά με τη μουσική;
5. Πιστεύετε ότι το πρόγραμμα αυτό σας βοήθησε με οποιοδήποτε τρόπο σε σχέση με τη θεραπεία σας για τον καρκίνο;
 - Πιστεύετε ότι η μουσικοθεραπεία επηρέασε με οποιοδήποτε τρόπο την ποιότητα ζωής σας και ειδικότερα α) τη διάθεση σας, β) την αίσθηση της ελπίδας, γ) την κούραση? Αν ναι, πώς;
6. Πως βιώσατε την παρουσία της θεραπεύτριας μέσα στη συνεδρία?
 - Τι ρόλο έπαιξε μέσα στη διαδικασία κατά τη γνώμη σας;
7. Επηρέασε η μουσικοθεραπεία άλλους τομείς της ζωής σας που δε σχετίζονται με την ασθένεια ή τη θεραπεία σας (πχ. Οικογενειακά θέματα, σχέσεις, κάποια άλλη κρίση ή τραυματικό γεγονός);
8. Κάτι άλλο που θα θέλατε να προσθέσετε;

Appendix L. Interview guide

(approximate English translation)

1. What made you choose (your motivation) to join this treatment and research program?
2. What was your overall impression of GIM?
3. When you think about how the project in general was structured, in terms of practical details: How did it work for you? Was there anything that could be better in terms of...

Follow up questions: recruitment process, time, setting, duration, number of sessions, frequency of sessions. Anything else?

4. Can you elaborate on your GIM experience? How was it for you and in what ways?

Follow up questions: positive or negative impact? Things that you liked/didn't like/ Comment on the music and its role, how did it work for you? what did you like/not like about it.

How was the experience of GIM during the chemotherapy period?

5. Did the program in any way help/aid you in relation to your treatment of the cancer?

Did the GIM treatment in any way affect your quality of life and in particular your mood, sense of hope, fatigue? If so, how?

6. How did you experience the therapist's presence during the session?
(In your opinion what role did the therapist played in the process?)
7. Did GIM affect other domains of your life not directly related to the treatment in relation with themes not related directly to the treatment (domestic issues, traumatic experiences, life crises etc.).
8. Anything else you would like to add?

Appendix M. Profile of Mood States (POMS-brief)

POMS (σύντομη έκδοση)

Περιγράψτε πως αισθανθήκατε την τελευταία εβδομάδα, συμπληρώνοντας τη λίστα που ακολουθεί. Χρησιμοποιήστε την ακόλουθη κλίμακα για να δηλώσετε το βαθμό στον οποίο σας εκφράζει η κάθε λέξη.

0 = Καθόλου, 1 = Λίγο, 2 = Ως ένα βαθμό, 3 = Αρκετά, 4 = Πάρα πολύ

1. σε ένταση	0	1	2	3	4
2. κουρασμένος/η	0	1	2	3	4
3. φιλικός/η	0	1	2	3	4
4. αβοήθητος/η	0	1	2	3	4
5. θυμωμένος/η	0	1	2	3	4
6. ακμαίος/α	0	1	2	3	4
7. δυσκολία να συγκεντρωθώ	0	1	2	3	4
8. νευρικός/η	0	1	2	3	4
9. εξαντλημένος/η	0	1	2	3	4
10. δυστυχισμένος/η	0	1	2	3	4
11. χαρούμενος/η	0	1	2	3	4
12. φθονερός/η	0	1	2	3	4
13. δραστήριος/α	0	1	2	3	4
14. δυσκολία να σκεφτώ ξεκάθαρα	0	1	2	3	4
15. αγχωμένος/η	0	1	2	3	4
16. εξουθενωμένος/η	0	1	2	3	4
17. χωρίς αξία	0	1	2	3	4
18. συμπονετικός/η	0	1	2	3	4
19. γκρινιάρης/α	0	1	2	3	4
20. ενεργητικός/η	0	1	2	3	4
21. ξεχασιάρης/α	0	1	2	3	4
22. χωρίς ελπίδα	0	1	2	3	4
23. μπερδεμένος/η	0	1	2	3	4
24. μετανιωμένος/η	0	1	2	3	4
25. πανικοβλημένος/η	0	1	2	3	4
26. μονάχος/η	0	1	2	3	4
27. εξαπατημένος/η	0	1	2	3	4
28. ευερέθιστος/η	0	1	2	3	4
29. πικραμένος/η	0	1	2	3	4
30. αποθαρρυνμένος/η	0	1	2	3	4

I

Appendix N. Cancer Fatigue Scale (CFS)

The Cancer Fatigue Scale

Αυτό το ερωτηματολόγιο θα σας υποβάλλει ερωτήσεις σχετικές με το αίσθημα κόπωσης που πιθανόν να βιώνετε. Για κάθε ερώτηση παρακαλώ βάλτε σε κύκλο μόνο ένα αριθμό, ο οποίος πιστεύετε ότι περιγράφει καλύτερα την παρούσα κατάσταση σας. Προσπαθήστε να απαντήσετε αυθόρμητα στις ερωτήσεις.

Αρ.	Αυτή τη στιγμή...	Όχι (1)	Λίγο (2)	Κάπως (3)	Αρκετά (4)	Πάρα πολύ (5)
1	Κουράζεστε εύκολα;					
2	Μήπως έχετε την παρόρμηση για να ξαπλώνετε;					
3	Νιώθετε εξαντλημένοι;					
4	Νιώθετε ότι έχετε καταστεί απρόσεκτοι;					
5	Νιώθετε ενεργητικοί;					
6	Μήπως αισθάνεστε το σώμα σας βαρύ και κουρασμένο;					
7	Νιώθετε ότι συχνά κάνετε λάθη ενόσω μιλάτε;					
8	Νιώθετε ενδιαφέρον για κάτι;					
9	Νιώθετε μπουχτισμένοι;					
10	Νιώθετε ότι έχετε καταστεί ξεχασιάρη;					
11	Μπορείτε να συγκεντρωθείτε σε συγκεκριμένα πράγματα;					
12	Νιώθετε διστακτικός;					
13	Νιώθετε ότι έχει επιβραδυνθεί η σκέψη σας;					
14	Μπορείτε να ενθαρρύνετε τον εαυτό σας να κάνει κάτι;					
15	Νιώθετε τόσο κόπωση που δεν ξέρετε τι να κάνετε με τον εαυτό σας;					

Appendix O. Herth Hope Index (HHI)

A.A. _____ Εβδομάδα

HERTH HOPE INDEX

Παρακάτω θα βρείτε μια λίστα με καταστάσεις. Διαβάστε κάθε μια χωριστά και βάλτε ένα [X] στο κουτί που περιγράφει καλύτερα αυτό με το οποίο συμφωνείτε περισσότερο αυτή τη στιγμή.

	Διαφωνώ πλήρως	Διαφωνώ	Συμφωνώ	Συμφωνώ πλήρως
1. Έχω θετική στάση απέναντι στη ζωή.				
2. Έχω βραχυπρόθεσμους ή/και μακροπρόθεσμους στόχους.				
3. Αισθάνομαι εντελώς μόνη.				
4. Μπορώ να δω τις δυνατότητες εν μέσω δυσκολιών.				
5. Έχω πίστη που με κάνει να νιώθω καλά.				
6. Αισθάνομαι φοβισμένη για το μέλλον μου.				
7. Μπορώ να αναπολώ ευχάριστες/χαρούμενες στιγμές.				
8. Έχω βαθιά, εσωτερική δύναμη.				
9. Είμαι σε θέση να δώσω και να λάβω φροντίδα και αγάπη.				
10. Έχω μια αίσθηση προσανατολισμού στη ζωή μου.				
11. Πιστεύω ότι κάθε μέρα έχει δυνατότητες.				
12. Πιστεύω ότι η ζωή μου έχει νόημα και αξία.				

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Appendix P. Visual Analogue Scales (VAS) for Fatigue and Hope

Α.Α..... εβδομάδα....

Visual Analogue Scales για την ελπίδα και την κούραση

Συμπληρώστε τις παρακάτω κλίμακες μαρκάροντας με **X** στο σημείο που σας αντιπροσωπεύει αυτή τη στιγμή

Απελπισμένη γεμάτη ελπίδα

Εξαιρετικά κουρασμένη Εντελώς ξεκούραστη

APPENDICES

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